From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/18/2020 2:10:43 AM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner Keith Gottesdiener I (b) (6) (b)(6)Eric Hughes (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy (b) (6) Sandeep Amanda Peppercorn | Menon | (b)(6)(b)(6)Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn (b)(6)Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Bascles, Lionel Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Michael ]; Desrosiers, Betsy | (b) (6) (b) (6) CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lucas Smalldon Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Kelly Beazley Wung, Peter /US | Subject: Follow-up to ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting Attachments: 2020-04-16\_TX-Clinical\_WG\_Master\_Protocols\_Subgroup\_Summary.pdf

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you all for your incredible help this week. I hope you all have a nice weekend and are able to get some rest!

Please find attached the final formal summary of our 2<sup>nd</sup> Subgroup call. Please review and let me know if you have any additions or amendments.

The co-chairs, subgroup chair, and I will be hard at work over the weekend on some materials. We look forward to sharing them with you all on Monday for our continued discussion. Please do not hesitate to reach out if you have any questions in the meantime!

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 4/16/2020 12:49:19 PM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | Eisner, Mark | Gottesdiener, Keith (b) (6) (b)(6)(b)(6)Hughes, Eric | (b) (6) **Judy Currier** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth (b)(6)Levy, Elliot I LaVange, Lisa | (b) (6) Mellors, John W (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b)(6)Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | Peppercorn, Amanda [ Poole, Mike (b)(6)(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ]; Kurilla, Michael (NIH/NCATS) [E] (b) (6) ]; Jansen, Kathrin [ (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John Biggs, Mary (b) (6) Butcher, Tina [ (b) (6) (b) (6) Demarcus | (b) (6) Macone, Erin [ Melencio, Cheryl (FNIH) [T] (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp); James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan ]; Tolman, Brett [ ]; Alvarez, Rosa (b) (6) (b)(6)Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Rose Li [ (b) (6) Dana Carluccio ]; Rose Li Central Account [FN Anderson, Margaret (b) (6) (b)(6)Lucas Smalldon | (b) (6) (b)(6)

Sent:

To:

CC:

Subject: ACTIV Therapeutics-Clinical Working Group Meeting #2

Attachments: ACTIV\_Therapeutics-Clinical\_MP Sub-Group Meeting 1\_Key Takeaways\_04152020v2.docx;

ACTIVPrioritizationCriteria-v2.xlsx; 2020-04-14\_TX-Clinical\_WG\_Agent\_Prioritization\_Subgroup\_Summary.pdf; ACTIV Therapeutics-Clinical WG Meeting Agenda\_04152020.pdf; ACTIV Therapeutics-Clinical WG 16Apr2020 Meeting

Guide 04152020.pdf

Location: https://zoom.us/ (b) (6)

**Start**: 4/16/2020 4:00:00 PM **End**: 4/16/2020 5:30:00 PM

Show Time As: Tentative

Required Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Attendees: Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;

Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH)

[T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER)

Optional Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas Attendees: (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Rose Li; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas

Smalldon

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

Thank you all for all your hard work this week. We cannot thank you enough for you time and dedication to this important effort. Today's large group meeting will serve for the two subgroups to come back together and provide updates to each other and ensure we are staying on a unified path to move forward for this workstream.

Please find attached the materials for today's meeting:

- 1. Agenda
- 2. Slides for the presentation
- 3. Formal summary for Agent Prioritization Subgroup − 1st Meeting
- 4. Draft Agent Prioritization Criteria/Data Needed (Excel Sheet)
- 5. High Level summary and action items for the Master Protocol Subgroup 1st Meeting

Note: The Master Protocol Subgroup will be having a second meeting immediately before this meeting, so we may be updating their summary slides on the fly during the meeting. Thank you for you patience and understanding with this fast moving process.

Reminder #1: If you are part of the Agent Prioritization Subgroup, we would like your feedback on the criteria in the Excel Spreadsheet attached.

Reminder #2: If you have not already done so, please fill out this Doodle Poll with your availability.

https://doodle.com/poll/nhd5zgimn537qqk5

Agent Prioritization Subgroup we especially need you to fill out for tomorrow as soon as you can.

If you have any questions, please do not hesitate to reach out.

Kind regards, Stacey, on Behalf of the TX-Clinical WG

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From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL] Sent: 9/9/2020 5:49:05 PM To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm] Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting Did you figure out how to make hover over work in a PDF? The PPTX file is working fine. ----Original Message----From: Parker, Ashley (NIH/OD) [E] < (b)(6)Sent: Wednesday, September 9, 2020 1:45 PM To: George, Jill (NIH/OD) [E] < (b) (b) (6) (b)(6)Brodd, Lauren (NIH/OD) [E] < Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting Hi Jill and Lauren, The clinical trial matrix is out for review by the ACTIV Tx working group. Jill -- Helen shared the attached PDF and I noticed the hover over does not work. I am not concerned about this issue given it's the WG reviewing but wanted to flag in case something needs to be tweaked in the PP file attached for future sharing using PDF. Thanks. Ashley ----Original Message----From: Chen, Helen Q. < (b) (6) Sent: Wednesday, September 9, 2020 1:2/ To: Adam, Stacey (FNIH) [T] (b)(6)Bozzette, Sam (NIH/NCATS) [E] < (b)(6)(b)(6)De Claro, R. Angelo (FDA/CDER) < (b) (6) Butterton, Joan < Draghia-Akli. Ruxandra < (b) (6) Eisner. Mark (b)(6)Gottesdiener, Keith (b) (6) (b)(6)Eric Hughes Judy Currier < (b) (6) Kim. Elizabeth < LaVange, Lisa < (b) (6) (b) (6) Levy, Elliot < (b)(6)Mellors, John W < (b) (6) Menon. Sandeep (b)(6)m>; Parker, Ashley (NIH/OD) (b) (6) Patel, Naimish |E| < (b)(6)(b)(6)Peppercorn, Amanda < Poole. Mike Proschan, Michael (NIH/NIAID) [E] (b) (b) (b)(6)Read, Sarah Santos, Michael (FNIH) [T] < (b) (6) (b)(6)(NIH/NIAID) |E| < Shen, Yuan Li Stein, Peter (FDA/CDER) < Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b)(6)(FDA/CDER) < (b) (6) .aov>: Wholley, David (FNIH) [T] < (b) (6) (b)(6)Collins, Sylva (b)(6)Amanda Peppercorn < (b) (6) (FDA/CDER) Garner, Carl (b)(6)Higgs. Elizabeth (NIH/NIAID) [El < (b)(6)Koroshetz, Walter (b) (6) (b) (6) (NIH/NINDS) [E] Timothy Burgess Reineck, Lora (b) (6) (NIH/NHLBI) [E] < Addarwal. Neil (NIH/NHLBI) [E] Rosenbera. Yves (NIH/NHLBI) [E] < (b) (6) Brown, Jerem .gov>: Goff. David (NIH/NHLBI) [E] (b) (6) [E] < Brown, Jeremy (NIH/NINDS) (b)(6)Gadbois, Ellen (NIH/OD) [E] Culp. Michelle (NIH/OD) [E] <michell Jacqueline Kirchner (b) (6) (b) (6) (b)(6)(b)(6)Beiael. John (NIH) [E] Phillips, L Revell CIV DTRA RD (USA) < (b) (6) Petrovick, Martha - 0449 -(b) (6) (b) (6) Sizemore, Christine (NIH/FIC) [E] (b)(6)>: Desrosiers. Betsy Christine (NIH/NCATS) [E] < CC: COIVIS. (b) (6) Kurilla, Michael (b) (6) Jansen. Kathrin < (b)(6)IEI (b) (6) (b)(6)Youna. John (NIH/NCATS) Lowv. Douglas (NCI) (b)(6)(b) (6) (b) (6) Bidas. Mary < Butcher, Tina < (b)(6)Macone. Erin <erinm@amden.com>: Melencio, Cheryl (FNIH) (b) (6) (b)(6)Tountas, Karen (FNIH) [T] Salathin, Carla < (b) (6) (b)(6)Menetski, Joseph (FNIH) ITI James. Stephanie (FNIH) (b) (6) (b)(6)>: btolman < Wachtel. Jonathan (b) (6) Alvarez. Rosa Maria < (b) (6) Gonzalez, Nina < (b) (6) Dana Carluccio (b)(6); Rose Li Central Account < (b)(6): Margaret Lucas Smalldon < (b) (6) (b)(6)Stratton, Anderson < (b) (6) Mollica. Linda /US Beniamin < (b)(6)(b)(6)Oashu. Felicia (NIH/OD) [E] <tel (b) (6) Patterson. Amv (NIH/NHLBI) [E] < Hilary (NIH/NIAID) |E| < Rubin. Daniel B. (FDA/CDER) (b) (6) (b) (6) Marston. (b)(6)Wung, Peter /US < (b)(6)Hoots, W. Keith (b)(6)(NIH/NHLBI) [E] < (b)(6)Groesch, Mary (NIH/NHLBI) [E] shipp,

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Allan (NIH/NHLBI) [E] <
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                       (b) (6) />; Hone, David M (Dave) CIV DTRA J9 (USA) < Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6)
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  Reisler.
                                                                                                                                                                                                       Freire, Maria (FNIH)
                            (b) (6)
                                                          Elsaid, Olivia <
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                                                                                                                   (b) (6)
                                                                                                                                                                                                           (b) (6)
   [T] <
  Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting
  Dear ACTIV TX-Clinical Working Group Members,
  As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported
  COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared
  more broadly once the information within it is public.
  We would appreciate your review of this draft version of the table, which we are sharing ahead of
  tomorrow's Working Group meeting. Please do not share the table or the information in it further.
  are looking forward to your input.
  Warm regards,
  Stacey, Mike, and Helen
From: Adam, Stacey (FNIH) [T] < (b)(6)

Sent: Wednesday, June 17, 2020 8:48 AM

To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel. John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b)(6) Sizemore, Christine (NIH/FIC) [E]
 Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio: Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin;

(b) (6) ; Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
  Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10. 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us (b)(6)
  Stacey Adam is inviting you to a scheduled Zoom meeting.
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Sent: 7/1/2020 3:05:14 AM

Subject: FW: Materials for July 1 ACTIV Partnership Leadership Call

Attachments: ACTIV Leadership Team Meeting 20200630 FINAL.pptx; 2020-06-03\_ACTIV\_Leadership\_Group\_Meeting\_Summary

Final.docx; Zoom instructions for July 1 2020 call final\_.docx

From: Melendo, Cherryl (FNIH)   T  <								
To: Austin, Christopher (NIH/NCATS) [E] < (b) (6)					<b>In Behalf Of</b> Wh	olley, David (	FNIH) [T]	
Marco   (b) (6)   Cihlar, Tomas   Ciblar, Mikeale   Ciblar, Richelle (NIH/OD)   E   Cibrow, Gary (OS/ASPR/BARDA)   Ciblar, Mikeale		(5.55)					a> (a>	
<ul> <li>(b) (6) Corey, Larry &lt; (b) (6) Culp, Michelle (NIH/DD) [E] &lt; (b) (6) Dolsterow, Gry (OS/ASPR/BARDA) &lt; (b) (6) Dolsterow, Mikael &lt; (b) (6) Freire, Maria (FNIH) [T] &lt; (b) (6) Gadbois, Ellen (NIH/DD) [E] &lt; (b) (6) Gibbons, Gary (NIH/NHLBI) [E]</li> <li>(b) (6) Johnson, Robert (OS/ASPR/BARDA) &lt; (b) (6) James, Stephanie (FNIH) [T]</li> <li>(b) (6) Johnson, Robert (OS/ASPR/BARDA) &lt; (b) (6) Lee, William &lt; (b) (6) Leopre, John &lt; (b) (6) Lane, Cliff (NIH/NIADD) [E] &lt; (b) (6) Lee, William &lt; (b) (6) Marston, Hilary (NIH/NIAD) [E] &lt; (b) (6) Marston, Hilary (NIH/NIADD) [E] &lt; (b) (6) Marston, Hilary (NIH/NIADD) [E] &lt; (b) (6) Marston, Hilary (NIH/NIADD) [E] &lt; (b) (6) Meeker, David (NIH/NIADD) [E] &lt; (b) (6) Meeker, David (NIH/NIADD) [E] &lt; (b) (6) Meeker, David (NIH/NIADD) [E] </li> <li>(b) (6) Pandya, Hitesh &lt; (b) (6) Pangalos, Mene &lt; (b) (6) Panglya, Hitesh &lt; (b) (6) Pandya, Hitesh &lt; (b) (6) Panglya, Mene &lt; (b) (6) Panglya, Mene &lt; (b) (6) Panglya, Steve &lt; (b) (6) Perlmutter, Roger &lt; (b) (6) Panglya, Steve &lt; (b) (6) Perlmutter, Roger &lt; (b) (6) Resee, David (NIH/NIADD) [E] &lt; (b) (6) Rouse, Doris &lt; (b) (6) Rouse, Doris &lt; (b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Skovronsky, Daniel &lt; (b) (6) Rouse, Doris &lt; (b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Stoffels, Paul </li> <li>(b) (6) Tabak, Lawrence (NIH/OD) [E] &lt; (b) (6) Talley, Michael </li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Virgin, Skig (NIH/OD) [E] &lt; (b) (6) Santos, Michael (NIH/OD) [E] &lt; (b) (6) Santos, Michael (NIH/OD) [E] &lt; (b) (6) Burklow, John (NIH/OD) [E] &lt; (b) (6) Gadbois, Ellen (NIH/OD) [E] &lt; (b) (6) Meltzer, Carrie (NIH/OD) [E] &lt; (b) (6) Goraalez, (NIH/OD) [E] &lt; (b) (6) Goraalez,</li></ul>	To: At	istin, Christo	pher (NIH/NCATS) [E]	(b) (6)	Carter, K	ara <	(b) (6)	Cavaleri,
Disbrow, Gary (OS/ASPR/BARDA) < (b) (6)	Marco	) <	(b) (6)	Cihlar, Iomas <	(b) (6)	C	ollins, Francis (I	VIH/OD) [E]
Emily (NIH/NIAID) [E] < (b) (6)								
FNIH	Disbro	ow, Gary (OS,	/ASPR/BARDA) <	(b) (6)	Dolsten, Mika	el <	(b) (6)	Erbelding,
<ul> <li>(b) (6)</li></ul>								
<ul> <li>(b) (6)</li></ul>	(FNIH)	) [T] < (	b) (6) Gadbois,	Ellen (NIH/OD) [E]	< (b) (6	) Gi	bbons, Gary (N	H/NHLBI) [E]
Company		(b) (6)	Hudson, Thom	as < (l	) (6)	James, Step	hanie (FNIH) [1	]
Lepore, John          (b) (6)         Marks, Peter (FDA/CBER)          (b) (6)         Marston, Hillary (NIH/NIAID) [E]          (b) (6)         Marston, Hillary (NIH/NIAID) [E]          (b) (6)         Meeker, David Meeker, David (NIH/NIAID) [E]          (b) (6)         Messonnier, Nancy (CDC/DDID/NCIRD/OD) (CPDID/NCIRD/OD) (CPDID/N		(b) (6)	Johnson, Robert (OS	s/ASPR/BARDA) <	(b) (6)	Kr	amer, Lynn	
(NIH/NIAID) [E] < (b) (6)								
<ul> <li>(b) (6)</li></ul>	Lepor	e, John <	(b) (6)	Marks, Peter (FDA,	/CBER) <	(b) (6)	Marsto	n, Hilary
<ul> <li>(b) (6) Pandya, Hitesh &lt; (b) (6) Pangalos, Mene</li> <li>(b) (6) Paul, Steve &lt; (b) (6) Perlmutter, Roger &lt; (b) (6) Rachel Ramoni</li> <li>(b) (6) Rasi, Guido &lt; (b) (6) Reed, John &lt; (b) (6) Reese, David &lt; (b) (6) Reses, David &lt; (b) (6) Rouse, Doris &lt; (b) (6) Sations, Michael (FNIH) [T] &lt; (b) (6) Skovronsky, Daniel &lt; (b) (6) Stein, Peter (FDA/CDER) &lt; (b) (6) Stoffels, Paul &lt; (b) (6) Talley, Michael</li> <li>(b) (6) Tabak, Lawrence (NIH/OD) [E] &lt; (b) (6) Talley, Michael</li> <li>(b) (6) Tabak, Lawrence (NIH/OD) [E] &lt; (b) (6) Talley, Michael</li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Woodcock, Janet (FDA/CDER)</li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Woodcock, Janet (FDA/CDER)</li> <li>(b) (6) Austin, Christopher (NIH/NCATS) [E] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Gadbois, Ellen (NIH/OD) [E] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Gadbois, Ellen (NIH/OD) [E] &lt; (b) (6) Hallett, Adrienne (NIH/OD) [E]</li> <li>(b) (6) Parker, Ashley (NIH/OD) [E] &lt; (b) (6) Myles, Renate (NIH/OD) [E]</li> <li>(b) (6) Desrosiers, Betsy &lt; (b) (6) Tabak, Lawrence (NIH/OD) [E]</li> <li>(b) (6) Desrosiers, Betsy &lt; (b) (6) Hughes, Eric</li> <li>(b) (6) Jansen, Kathrin &lt; (b) (6) Kurilla, Michael (NIH/NCATS) [E]</li> <li>(b) (6) Mallory, Raburn &lt; (b) (6) Anderson, Margaret</li> <li>(b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Menetski, Joseph (FNIH) [T]</li> <li>(b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Menetski, Joseph (FNIH) [T]</li> <li>(b) (6) Gorman, Greta (FNIH) [T] &lt; (b) (6) Myles, Renate (NIH/OD) [E]</li> <li>(b) (6) Gorman, Greta (FNIH) [T] &lt; (b) (6) Myles, Renate (NIH/OD) [E]</li> </ul>	(NIH/I	NIAID) [E] <	(b) (6)	Mascola, John	(NIH/VRC) [E] <	(b) (d	5) Me	eker, David
<ul> <li>(b) (6) Pandya, Hitesh &lt; (b) (6) Pangalos, Mene</li> <li>(b) (6) Paul, Steve &lt; (b) (6) Perlmutter, Roger &lt; (b) (6)</li> <li>Plenge, Robert &lt; (b) (6) Plump, Andy &lt; (b) (6) Rachel Ramoni</li> <li>(b) (6) Rasi, Guido &lt; (b) (6) Reed, John &lt; (b) (6) Reses, Davide (Nilly) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1</li></ul>	<	(b) (6)	Menetski, Josep	oh (FNIH) [T] <	(b) (6)	Messonnie	r, Nancy (CDC/I	ODID/NCIRD/OD)
<ul> <li>(b) (6) Paul, Steve &lt; (b) (6) Perlmutter, Roger &lt; (b) (6) Perlmutter, Roger &lt; (b) (6) Plump, Andy &lt; (b) (6) Rachel Ramoni</li> <li>(b) (6) Rasi, Guido &lt; (b) (6) Reed, John &lt; (b) (6) Reese, Davi</li> <li>(b) (6) Rouse, Doris &lt; (b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Skovronsky,</li> <li>Daniel &lt; (b) (6) Stein, Peter (FDA/CDER) &lt; (b) (6) Stoffels, Paul</li> <li>(b) (6) Tabak, Lawrence (NIH/DD) [E] &lt; (b) (6) Talley, Michael</li> <li>(b) (6) Tsai, John &lt; (b) (6) Vessey, Rupert &lt; (b) (6) Virgin, Ski</li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Woodcock, Janet (FDA/CDER)</li> <li>(b) (6) Woodley, David (FNIH) [T] &lt; (b) (6) Austin, Christopher (NIH/NCATS) [E] &lt; (b) (6) Burklow, John (NIH/DD) [E]</li> <li>(b) (6) Gadbois, Ellen (NIH/DD) [E] &lt; (b) (6) Hallett, Adrienne (NIH/DD) [E]</li> <li>(b) (6) Gadbois, Ellen (NIH/DD) [E] &lt; (b) (6) Myles, Renate (NIH/DD) [E]</li> <li>(b) (6) Parker, Ashley (NIH/DD) [E] &lt; (b) (6) Myles, Renate (NIH/DD) [E]</li> <li>(b) (6) Desrosiers, Betsy &lt; (b) (6) Tabak, Lawrence (NIH/NCATS) [E]</li> <li>(b) (6) Jansen, Kathrin &lt; (b) (6) Kurilla, Michael (NIH/NIADD) [E] &lt; (b) (6) Gorman, Kathrin &lt; (b) (6) Mallory, Raburn &lt; (b) (6) Anderson, Margaret</li> <li>(b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Menetski, Joseph (FNIH) [T]</li> <li>(b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Menetski, Joseph (FNIH) [T]</li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Burklow, John (NIH/DD) [E]</li> <li>(b) (6) Gorman, Greta (FNIH) [T] &lt; (b) (6) Burklow, John (NIH/DD) [E]</li> <li>(b) (6) Gorman, Greta (FNIH) [T] &lt; (b) (6) Myles, Renate (NIH/DD) [E]</li> </ul>	<	(b) (6)	Pandya, Hitesh <	(b) (6)	Pa	ngalos, Mene	;	
< (b) (6)         Paul, Steve          (b) (6)         Perlmutter, Roger          (b) (6)           Plenge, Robert          (b) (6)         Plump, Andy          (b) (6)         Rachel Ramon           < (b) (6)         Rasi, Guido          (b) (6)         Reed, John          (b) (6)         Reese, David           < (b) (6)         Rouse, Dorls          (b) (6)         Santos, Michael (FNIH) [T]          (b) (6)         Skorvonsky,           Daniel          (b) (6)         Stein, Peter (FDA/CDER)          (b) (6)         Stoffels, Paul           < (b) (6)         Tabak, Lawrence (NIH/OD) [E]          (b) (6)         Talley, Michael           < (b) (6)         Tsai, John          (b) (6)         Vessey, Rupert          (b) (6)         Virgin, Skij           < (b) (6)         Wholley, David (FNIH) [T]          (b) (6)         Woodcock, Janet (FDA/CDER)           < (b) (6)         Wholley, David (FNIH) [T]          (b) (6)         Anderson, James (NIH/OD) [E]           < (b) (6)         Austin, Christopher (NIH/NCATS) [E]          (b) (6)         Burklow, John (NIH/OD) [E]           < (b) (6)         Castillejos, Carlos          (b) (6)         Culp, Michaelle (NIH/OD) [E]           < (b) (6)         Gadbois, Ellen (NIH/NIAID) [E]          (b) (6)         Myles, Renate (NIH/OD) [E] <t< td=""><td>&lt;</td><td>(b)</td><td>(6) Pa</td><td>o, William &lt;</td><td>(b) (6)</td><td>Parker, A</td><td>Ashley (NIH/OD</td><td>) [E]</td></t<>	<	(b)	(6) Pa	o, William <	(b) (6)	Parker, A	Ashley (NIH/OD	) [E]
Plenge, Robert <   (b) (6)	<	(b) (6)	Paul, Steve <	(b) (6)	Perlmutter,	Roger <	(b) (6)	
<ul> <li>(b) (6) Rasi, Guido &lt; (b) (6) Reed, John &lt; (b) (6) Reese, Davi &lt; (b) (6) Rouse, Doris &lt; (b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Skovronsky, Daniel &lt; (b) (6) Tabak, Lawrence (NIH/OD) [E] &lt; (b) (6) Talley, Michael &lt; (b) (6) Tabak, Lawrence (NIH/OD) [E] &lt; (b) (6) Talley, Michael &lt; (b) (6) Tsai, John &lt; (b) (6) Vessey, Rupert &lt; (b) (6) Virgin, Ski &lt; (b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Woodcock, Janet (FDA/CDER)</li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Woodcock, Janet (FDA/CDER)</li> <li>(b) (6) Austin, Christopher (NIH/NCATS) [E] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Castillejos, Carlos &lt; (b) (6) Culp, Michelle (NIH/OD) [E]</li> <li>(b) (6) Castillejos, Carlos &lt; (b) (6) Hallett, Adrienne (NIH/OD) [E]</li> <li>(b) (6) Lane, Cliff (NIH/NIAID) [E] &lt; (b) (6) Hallett, Adrienne (NIH/OD) [E]</li> <li>(b) (6) Parker, Ashley (NIH/OD) [E] &lt; (b) (6) Myles, Renate (NIH/OD) [E]</li> <li>(b) (6) Desrosiers, Betsy &lt; (b) (6) Tabak, Lawrence (NIH/OD) [E]</li> <li>(b) (6) Desrosiers, Betsy &lt; (b) (6) Hughes, Eric</li> <li>(b) (6) Lowy, Douglas (NCI) &lt; (b) (6) Read, Sarah (NIH/NIAID) [E] &lt; (b) (6)</li> <li>Young, John &lt; (b) (6) Mallory, Raburn &lt; (b) (6)</li> <li>Cc: Adam, Stacey (FNIH) [T] &lt; (b) (6) Alvarez, Rosa &lt; (b) (6) Anderson, Margaret</li> <li>(b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Stratton, Ben &lt; (b) (6) Gonzalez, Nina &lt; (b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Gorman, Greta (FNIH) [T] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Gorman, Greta (FNIH) [T] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Myles, Renate (NIH/OD) [E]</li> </ul>	Plenge	e, Robert <	(b) (6)	Plump, Andy <	(b) (6)		Rachel Ramoni	
Daniel < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Stoffels, Paul < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Talley, Michael < (b) (6) Tsai, John < (b) (6) Vessey, Rupert < (b) (6) Virgin, Ski < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER) < (b) (6) Young, John < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Hallett, Adrienne (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Busnoisers, Betsy < (b) (6) Hughes, Eric < (b) (6) Desrosiers, Betsy < (b) (6) Hughes, Eric < (b) (6) Dasnen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Gadam, Stacey (FNIH) [T] < (b) (6) Mallory, Raburn < (b) (6) Anderson, Margaret < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Gorman, Brett < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Mentzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]	<	(b) (6)	Rasi, Guido <	(b) (6)	Reed	d, John <	(b) (6)	Reese, Davi
Daniel < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) Stoffels, Paul < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Talley, Michael < (b) (6) Tsai, John < (b) (6) Vessey, Rupert < (b) (6) Virgin, Ski < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER) < (b) (6) Young, John < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) Hallett, Adrienne (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Busnoisers, Betsy < (b) (6) Hughes, Eric < (b) (6) Desrosiers, Betsy < (b) (6) Hughes, Eric < (b) (6) Dasnen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Gadam, Stacey (FNIH) [T] < (b) (6) Mallory, Raburn < (b) (6) Anderson, Margaret < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Gorman, Brett < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Burklow, John (NIH/OD) [E] < (b) (6) Mentzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Myles, Renate (NIH/OD) [E] < (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]	<	(b) (6)	Rouse, Doris <	(b) (6) San	tos, Michael (FN	IIH) [T] <	(b) (6)	Skovronsky,
<ul> <li>(b) (6) Tabak, Lawrence (NIH/OD) [E] &lt; (b) (6) Talley, Michael</li> <li>(b) (6) Tsai, John &lt; (b) (6) Vessey, Rupert &lt; (b) (6) Virgin, Skij</li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Woodcock, Janet (FDA/CDER)</li> <li>(b) (6) Young, John &lt; (b) (6) Anderson, James (NIH/OD) [E]</li> <li>(b) (6) Austin, Christopher (NIH/NCATS) [E] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Castillejos, Carlos &lt; (b) (6) Culp, Michelle (NIH/OD) [E]</li> <li>(b) (6) Gadbois, Ellen (NIH/OD) [E] &lt; (b) (6) Hallett, Adrienne (NIH/OD) [E]</li> <li>(b) (6) Lane, Cliff (NIH/NIAD) [E] &lt; (b) (6) Myles, Renate (NIH/OD) [E]</li> <li>(b) (6) Parker, Ashley (NIH/OD) [E] &lt; (b) (6) Tabak, Lawrence (NIH/OD) [E]</li> <li>(b) (6) Posrosiers, Betsy &lt; (b) (6) Tabak, Lawrence (NIH/OD) [E]</li> <li>(b) (6) Desrosiers, Betsy &lt; (b) (6) Hughes, Eric</li> <li>(b) (6) Jansen, Kathrin &lt; (b) (6) Kurilla, Michael (NIH/NCATS) [E]</li> <li>(b) (6) Lowy, Douglas (NCI) &lt; (b) (6) Read, Sarah (NIH/NIAID) [E] &lt; (b) (6)</li> <li>Young, John &lt; (b) (6) Mallory, Raburn &lt; (b) (6) Anderson, Margaret</li> <li>(b) (6) Anderson, Margaret</li> <li>(b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Menetski, Joseph (FNIH) [T]</li> <li>(b) (6) Santos, Michael (FNIH) [T] &lt; (b) (6) Menetski, Joseph (FNIH) [T]</li> <li>(b) (6) Wachtel, Jonathan</li> <li>(b) (6) Wholley, David (FNIH) [T] &lt; (b) (6) Burklow, John (NIH/OD) [E]</li> <li>(b) (6) Gorman, Greta (FNIH) [T] &lt; (b) (6) Myles, Renate (NIH/OD) [E]</li> </ul>	Danie	l <	(b) (6) S	tein, Peter (FDA/C	DER) <	(b) (6)	Stoffels, P	aul
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Subject: Materials for July 1 ACTIV Partnership Leadership Call

#### Dear Colleagues:

Thank you very much for taking time to join Francis Collins, Paul Stoffels, and the rest of our Executive Committee tomorrow, July 1, from 1:00 p.m. – 2:30 p.m. Eastern U.S. time to discuss the progress of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership since our last call on June 3. You should have received a calendar invitation for the teleconference, which FNIH will be hosting. Please contact Cheryl Melencio and Joe Menetski at FNIH if you have any issues preparing for or signing into Zoom for the teleconference ( (b) (6) or (b) (6)

Attached you will find the following materials for the meeting:

- 1) The PowerPoint slide deck for the meeting, which includes the meeting agenda
- 2) The meeting minutes from our June 3 meeting (previously sent to you on June 4)
- 3) Instructions on how to use the Zoom app to access and participate in the meeting.

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We look forward to speaking with you tomorrow and hearing your feedback.
Join Zoom Meeting
https://fnih.zoom.
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Dial by your location
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# Regards,

David Wholley Senior Vice President, Research Partnerships Foundation for the National Institutes of Health From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 8/28/2020 2:27:04 PM To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil] Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference Thanks! The vaccines and CT capacity WG are done but I will move the checks! From: George, Jill (NIH/OD) [E] < (b)(6)Sent: Friday, August 28, 2020 9:45 AM To: Parker, Ashley (NIH/OD) [E] < (b)(6)Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference Thanks for converting! Pretty soon you won't need me at all! (3) Move the animated the checks as needed. Made a logical assumption, but could be wrong! Jill From: Parker, Ashley (NIH/OD) [E] (b)(6)Sent: Friday, August 28, 2020 9:15 AM To: George, Jill (NIH/OD) [E] (b)(6)Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference I converted them PP. From: George, Jill (NIH/OD) [E] (b) (6) Sent: Friday, August 28, 2020 9:12 AM To: Parker, Ashley (NIH/OD) [E] < (b) (6) Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference Darn. These are all PDFs. Any PPTX files? From: Parker, Ashley (NIH/OD) [E] (b)(6)Sent: Friday, August 28, 2020 8:49 AM To: George, Jill (NIH/OD) [E] < (b)(6)Subject: FW: Materials for August 26 ACTIV Partnership Leadership Team Teleconference Importance: High From: Melencio, Cheryl (FNIH) [T] On Behalf Of Wholley, David (FNIH) [T] (b) (6) Sent: Tuesday, August 25, 2020 9:47 PM To: Austin, Christopher (NIH/NCATS) [E] (b)(6); Bancel, Stephane (b)(6)(b)(6); Carter, Kara ; Cavaleri, Marco Cihlar, Tomas < Collins, Francis (NIH/OD) [E] (b)(6)>; Culp, Michelle (NIH/OD) [E] : Corey, Larry (b)(6)(b)(6)(b) (6) Disbrow, Gary (OS/ASPR/BARDA) < Dolsten, Mikael < (b) (6) (b) (6) ; Erbelding, Emily (NIH/NIAID) [E] < ; Erck, Stan ; Fauci, Anthony (NIH/NIAID) [E] (b)(6)(b) (6)

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Freire, Maria (FNIH) [T]

: Gibbons, Gary (NIH/NHLBI) [E]

>; Gadbois, Ellen (NIH/OD) [E]

>; Hudson, Thomas

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Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

### Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

Join Zoom Meeting

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent: 4/10/2020 2:54:23 PM

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wood, Gretchen

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]

Subject: RE: Other Companies to give a heads up

Suggestions as to the message to convey? Are we open to adding other members to the WGs?

FC

From: Wholley, David (FNIH) [T] < (b) (6)

Sent: Friday, April 10, 2020 10:40 AM

To: Collins, Francis (NIH/OD) [E] < (b) (6)

Cc: Menetski, Joseph (FNIH) [T] < (b) (6) Wood, Gretchen (NIH/OD) [E] < (b) (6)

Subject: FW: Other Companies to give a heads up

Francis, here are the major folks to reach out to (thanks to Joe Menetski for this):

Regeneron - George Yancopoulos (b) (6)

Gilead - William Lee (b) (6)

Eisai - Lynn Kramer (was on Rupert Vessey's list of folks to include on TX list but we did not have room). He's VP, Chief

Clinical Officer, Neurology Business Group (b) (6)

Biogen - Al Sandrock (b) (6)
Abbvie – Tom Hudson (b) (6)

Lilly – Dan Skovronsky (b) (6) George Scangos (now at Vir) (b

Amgen – David Reese (you can thank him for participation of Elliott Levy (SVP Global Devt) on the TX-Therapeutics WG. He is part of the Vessey/Plump group but worth reaching out to directly—and a great partnership person, by the

way) (b) (6)

Additions: Perhaps Stephane Bancel at Moderna, given the partnership with NIH? I have also not included anyone from Boehringer-Ingelheim or Bayer. Shall we try to get you those names and email addresses?

David

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Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
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           (b) (6)
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                      Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; HSchuite@its.jnj.com;
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se];
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Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen
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                                                 Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
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                              Isabel Ramsey |
                                                                            Parker, Ashley (NIH/OD) [E]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary
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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Hughes, Eric | Kurilla, Michael (NIH/NCATS) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Paul Gillard I (b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli.Hamill; Modiarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) [ (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Stratton, Benjamin [ Wachtel, Jonathan (b) (6) (b) (6) Anderson, Margaret marga (b)(6)rose. (b) (6) dana.car (b)(6)**Bethany Stokes** Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta] Subject: Canceled: ACTIV Vaccines Working Group meeting Location: Webex: https://nih.webex. (b) (6) Start: 6/9/2020 4:00:00 AM End: 6/10/2020 4:00:00 AM Show Time As: Free

Required	(b) (6	) Lowy, D	ouglas (NIH/NCI	) [E];	(b) (6)	Arvin, An	n; Beth Bell
Attendees:	( (b) (6)	(b	) (6)	Cavaleri Marco;	(b) (6)		
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	Barton; (b)	(6) (t	o) (6) N	Marks, Peter (FDA,	(CBER); Mascola	a, John (NIH/VF	RC) [E];
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	(b) (6)	Seals, Jonatha	an (OS/ASPR/BAI	RDA); (t	0) (6)	Tal Zaks	
Optional	Tolman, Brett;	(b) (6)	Hopps, M	arkay; Kozlowski,	Mary (NIH/NCI	) [C]; Johnson,	Maureen
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	(b) (6)	Austin, Sa	rah (NIH/NIAID)	[E];	(b) (6)	Isabel Ra	msey; Parker,
	Ashley (NIH/OD)	[E]; Marston, Hilary	(NIH/NIAID) [E]	; Qashu, Felicia (N	IIH/OD) [E]; Cul	p, Michelle (NI	H/OD) [E];
	Gadbois, Ellen (N	NIH/OD) [E]; Wholley	, David (FNIH) [	Γ]; Melencio, Che	ryl (FNIH) [T]; N	lenetski, Josep	h (FNIH) [T];
	Adam, Stacey (FI	NIH) [T]; Tountas, Ka	ren (FNIH) [T]; J	ames, Stephanie	(FNIH) [T]; Colvi	s, Christine (NI	H/NCATS) [E];
	Desrosiers, Bets	y; Hughes, Eric; Kuril	la, Michael (NIH	/NCATS) [E]; Read	d, Sarah (NIH/NI	AID) [E]; Young	g, John; Paul
	Gillard; Hamilton	n, Holli (OS/ASPR/BA	RDA); Modjarra	d, Kayvon CIV US	ARMY MEDCON	WRAIR (USA);	Kathleen Neuzil
	Schrag, Stephan	ie (CDC/DDID/NCIRD	)/DBD); Verani, J	ennifer R. (CDC/D	DDID/NCIRD/DB	D); Thornburg,	Natalie
	(CDC/DDID/NCIF	RD/DVD); Gonzalez,	Nina; Wachtel, J	onathan; Stratton	, Benjamin; And	derson, Margar	ret;
	(b) (d	5)	(b) (6)	B	ethany Stokes;	Ann Arvin	

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/4/2020 9:19:15 PM To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ Butterton, Joan ]; Collins, Sylva (FDA/CDER) (b) (6) (b)(6)De Claro, R. Angelo (FDA/CDER) | Mark Eisner (b) (6) (b)(6)Keith Gottesdiener [ (b)(6)Eric Hughes (b)(6)LaVange, Lisa M [ Elliott Levy [ Sandeep (b)(6)(b) (6) (b) (6) Menon I Amanda Peppercorn | Proschan, Michael (b)(6)(b) (6) (NIH/NIAID) [E] [ (b)(6)Read, Sarah (NIH/NIAID) [E] | (b)(6)Amanda Peppercorn Price, Dionne (FDA/CDER) | (b)(6)Rubin, Daniel B. (b)(6)(FDA/CDER) [ Shen, Yuan Li (FDA/CDER) | Farley, John (b) (6) (b)(6)(FDA/CDER) ]; Goff, David (NIH/NHLBI) [E] [ ]; Vincent, Michael (b) (6) (b) (6) (b)(6)Wung, Peter /US | (b) (6) Karen Lynn Price (b)(6)]; Koroshetz, Walter (NIH/NINDS) [E] [ (b) (6) ]; Patterson, Amy (NIH/NHLBI) [E] | (b)(6)**Judy Currier** (b)(6)Pamela Tenaerts, M.D. (b)(6)CC: Mary Biggs | Macone, Erin I (b)(6)Demarcus I (b)(6)(b) (6) Tountas, Karen (FNIH) [T] [ Wachtel, Jonathan Elizabeth Kim (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [ Melencio, Cheryl (FNIH) [T] (b) (6) (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] | (b) (6) (b) (6) Subject: ACTIV TX-Clinical Master Protocol Ad Hoc Meeting Location: https://fnih.zoom. (b) (6) Start: 5/5/2020 6:00:00 PM End: 5/5/2020 7:00:00 PM Show Time As: Busy Required Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Attendees: Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter/US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]; Patterson, Amy (NIH/NHLBI) [E] Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Hoots, W. Keith (NIH/NHLBI) [E] Stacey Adam is inviting you to a scheduled Zoom meeting. Join Zoom Meeting (b)(6)https://fnih.zoom.us/ Meeting ID: (b)(6)Password: (b) (6) One tan mobile (b)(6)US (New York)

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(b) (6)
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/19/2020 8:39:51 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | Eisner, Mark | Gottesdiener, Keith (b) (6) (b) (6) (b)(6)Hughes, Eric | (b) (6) **Judy Currier** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth (b) (6) Levy, Elliot I LaVange, Lisa | (b) (6) Mellors, John W (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | Peppercorn, Amanda [ Poole, Mike (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn (b) (6) CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp] Subject: Time Sensitive Request for Response from ACTIV Therapeutics-Clinical Working Group Dear ACTIV Therapeutics-Clinical Working Group Members, I hope this message finds you well. I am writing to seek your approval to publicly list your name in association with this ACTIV working group. A reporter has reached out to the FNIH asking for the names of the working group members, and we would like to point them to a listing of these names on the FNIH website, once you have provided clearance for this. The FNIH's Vice President of Communications and Events, Abbey Meltzer, will be tracking these approvals, so please send your approval to her at (b) (6) . If you have any questions, please do not hesitate to reach out to Abbey.

Stacey J. Adam, PhD

Best, Stacey Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) | Mobile:

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

(b) (6)

f in a s

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From:

Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent:

4/20/2020 1:54:12 PM

To:

Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject:

Re: Clinical Trial Capacity WG - meeting #1 summary

Attachments: Master and WG Email List for ACTIV rv 042020.xlsx

### Good morning Cheryl,

The attached list has Robert Johnson added to the master list and Rick Bright is removed. I standby on adding him to the WG's until we hear back from Francis.

Thanks, Ashley

From: Wholley, David (FNIH) [T] < (b)(6)

Sent: Monday, April 20, 2020 9:27 AM

To: Melencio, Cheryl (FNIH) [T] < (b)(6)Gonzalez, Nina < (b)(6)Stratton, Benjamin

< (b)(6)James, Stephanie (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] (b)(6)< Santos, Michael (FNIH) [T] < Parker, Ashley (NIH/OD) [E] (b) (6)

(b)(6): Adam, Stacey (FNIH) [T] < (b)(6)Tountas, Karen (FNIH) [T] < (b) (6)

Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Can we please send an invitation to Robert Johnson to attend the Wednesday ACTIV leadership group call? He will likely be replacing Rick Bright on that call, but we won't know for sure until Francis Collins has had a few more conversations.

From: Johnson, Robert (OS/ASPR/BARDA) < (b)(6)

Sent: Monday, April 20, 2020 7:04 AM

(b)(6)To: Wholley, David (FNIH) [T]

Cc: Tountas, Karen (FNIH) [T] Walker, Robert (OS/ASPR/BARDA) < (b) (6)

Subject: RE: Clinical Trial Capacity WG - meeting #1 summary

David,

Hi and thanks for the follow-up. your assessment aligns with mine-so it's okay if we remove Jim from the list of participants for this WG?

Thanks.

Robert

### Robert Johnson, Ph.D.

Director, Influenza and Emerging Infectious Diseases Division Biomedical Advanced Research and Development Authority

#### BARDA

Assistant Secretary for Preparedness and Response ASPR Department of Health and Human Services

330 Independence Avenue, S.W. Room 640 G

Washington, D.C. 20201

Office: (b) (6) Cell: (b) (6)

email: (b) (6)

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From: Wholley, David (FNIH) [T] < (b) (6)

Sent: Sunday, April 19, 2020 7:12 AM

To: Johnson, Robert (OS/ASPR/BARDA) < (b) (6)

Cc: Tountas, Karen (FNIH) [T] < (b) (6)

Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Hi Robert, Karen Tountas forwarded me your note below. Francis Collins asked Rick Bright for names for three of the groups—Clinical TX, Preclinical TX, and Vaccines. There was no request for a BARDA representative for the Clinical Trial Capacity group that I'm aware of, although if BARDA wanted to add one I'm sure there would be no objection. David Wholley

From: Johnson, Robert (OS/ASPR/BARDA) (b) (6)

Sent: Sunday, April 19, 2020 6:55 AM

To: Tountas, Karen (FNIH) [T] < (b) (6)

Cc: Walker, Robert (OS/ASPR/BARDA) (b) (6) King, James (OS/ASPR/BARDA)

(b) (6) ; Johnson, Robert (OS/ASPR/BARDA) (b) (6)

Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Karen,

Good morning. My name is Robert Johnson and I serve as the IMT manager for the COVID-19 response in BARDA. I'm trying to sort something out and hope you can help. Last weekend BARDA was asked to provide names of individuals to sit on three of the four PPP WGs. We were not asked to provide a name for the fourth working group, Clinical Trial Capacity, so we did not put one forth. I am not sure how Dr. King's name was added to the roster. Can you please clarify if BARDA is being requested to add someone to this WG? If so, we'll circle back with a name.

Thank you.

Robert

#### Robert Johnson, Ph.D.

Director, Influenza and Emerging Infectious Diseases Division Biomedical Advanced Research and Development Authority

#### BARDA

Assistant Secretary for Preparedness and Response ASPR Department of Health and Human Services 330 Independence Avenue, S.W. Room 640 G

Washington, D.C. 20201

Office: (b) (6) Cell: (b) (6)

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From: King, James (OS/ASPR/BARDA) (b) (6)

Sent: Friday, April 17, 2020 8:21 AM

To: Johnson, Robert (OS/ASPR/BARDA) < (b) (6)

Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

I will send this to you and I will call.

Jim King

From:	Tountas, Kare	n (FNIH) [T] (b)	(6)				
Sent:	Thursday, Apri	16, 2020 11:46 AM					
To: Ba	scles, Lionel <	(b) (6)	Cohen,	Myron	(b) (6)	>; C	orey, Larry
<	(b) (6)	Desrosiers , Bets	y	(b) (6)	Dicke	ns, Jim (NIH/I	NCATS) [C]
<	(b) (6)	; Doroshow, Jam	es (NIH/NCI) [E]	(b) (6	5) >; 6	off, David (N	IH/NHLBI) [E]
<	(b) (6)	King, James (OS/AS	PR/BARDA) <	(b) (6)	: Kurilla, I	Michael (NIH/	/NIAID) [E]
<	(b) (6)	Nayak, Seema (	NIH/NIAID) [E] <	(b) (6)	) Par	ker, Ashley (N	NIH/NCI) [F]
<	(b) (6)	; Payton, Manizh	e (NIH/NIAID) [E	(b)	(6)	; Resnansky,	Laura
	(b) (6)	Srinivasan,	Badhri <	(b) (6)	S	tein, Peter (Fl	DA/CDER)
<	(b) (6)	Vincent, Mike	(b)	(6)	; Woodcock,	Janet (FDA/C	CDER)
	(b) (6)						
Cc: Co		NIH/NCATS) [E] <	(b) (6)	Hughes, Eri	c (l	b) (6)	; Jansen, Katl
<	(b) (6)	Lowy, Doug	las (NCI) < (	(b) (6) Rea	ad, Sarah (NIH,	/NIAID) [E]	
	(b) (6)	Young, John	(b) (6)	; Crif	field, Robin	(b)	) (6)
Hamil	ton, Nancy	(b) (6)	Mele	ncio, Cheryl (FI	> [T] (HIV	(b) (6)	Minnich, Be
<	(b) (6)		(NIH/NCATS) [E	[] < (b)	(6) T	homas, Ashle	y (FDA/CDER)
	(b) (6)	; Adam, Sta	cey (FNIH) [T]	(b) (6)	>; Anderson	, Margaret	
			Dana <	(b) (6)		Melencio,	Cheryl (FNIH) [T
<	(b) (6)	Gonzalez, Nina	(b) (6)	He	aton, Penny <	(b	0) (6)
James	, Stephanie (FN	NIH) [T] (b) (6)	; Li, Rose	(b)	(6)	; Menetski,	Joseph (FNIH) [T
	(b) (6)	>; Santos, Michael (FN	VIH) [T] (t	o) (6) >; 7	Tuvesson, Nan	су	
	(b)	(6) ;	Wholley, David	(FNIH) [T]	(b) (6)	; Wachtel,	, Jonathan
	(b) (6)		200	24 (2017) S.			
Subje	t: RE: Clinical	Trial Capacity WG - me	eting #1 summa	ary			
5.5							

Apologies, attached is a cleaner version. Karen

From: Tountas, Karen (FNIH) [T]
Sent: Thursday, April 16, 2020 6:10 AM

To: Bascles, Lionel <	(b) (6)	Cohen, Myron		(b) (6)	Corey, Larry
(b) (6)	; Desrosiers , Betsy <	(b) (6)		>; Dickens, J	im (NIH/NCATS) [C]
(b) (6) >; Doroshow, James (NIH		IH/NCI) [E] <	(b) (6)	Goff,	David (NIH/NHLBI) [E]

<	(b) (6)	King, Jame	s <	(b) (6)	; Kur	illa, Mike	<	(b) (6)	Naya	ak, Seema (NIH/NIAID
[E] <see< td=""><td>ema.naya(b) (6)</td><td>.gov&gt;; Park</td><td>er, Ashley</td><td>(NIH/OD) [E]</td><td></td><td>(b) (6)</td><td></td><td>&gt;; Payto</td><td>n, Manzi</td><td>ne</td></see<>	ema.naya(b) (6)	.gov>; Park	er, Ashley	(NIH/OD) [E]		(b) (6)		>; Payto	n, Manzi	ne
	(b) (6)	>; Resna	ansky, Lau	ra	(b) (6)		>; Srir	nivasan, E	Badhri	
				eter (FDA/CD						Mike
	(b) (6)	>; \	Voodcock,	Janet (FDA/C	DER)		(b) (e	5)		
Cc: Col	vis, Christine (N	IH/NCATS)	[E]	(b) (6)		; Hughes,	Eric	(	b) (6)	>; Jansen,
Kathrin	(b)	(6)	>; Lowy	, Douglas (NC	(1) <	(b) (6)	>; Rea	ad, Sarah	(NIH/NIA	AID) [E]
	(b) (6)									
Hamilto	on, Nancy	(b)	(6)	>; Mel	encio,	Cheryl (FN	IIH) [T]	<	(b) (6)	; Minnich, Beth
	(b) (6)	Rebe	ecca (NIH/	NCATS) Katz [	E] (			(b) (6)		Thomas,
Ashley	(FDA/CDER)	(b	(6)	>; Adar	n, Stac	ey (FNIH)	[T]	(b) (6)	>; A	nderson, Margaret
<	(b) (6)	(	Carluccio,	Dana		(b) (6)			Cheryl (F	NIH) Melencio [T]
	(b)	(6)		Gonzalez, I	Vina	(	b) (6)		>; Heato	n, Penny
	(b) (6)	; J.	ames, Step	hanie <	(b) (6)	Li,	Rose <		(b) (6)	
Menets	ki, Joseph (FNII	H) [T] <	(b) (6)	Santo	s, Mic	hael (FNIH	) <	(b) (6)	Т	uvesson, Nancy
	(b) (6	)	; V	Vholley, David	d (FNIF	I) [T]	(b) (	6)	Wachte	el, Jonathan

Subject: Clinical Trial Capacity WG - meeting #1 summary

Dear Clinical Trial Capacity Working Group colleagues,

Attached is a summary of meeting #1 of the Clinical Trial Capacity Working Group. It was a very good start to this effort; thank you to everyone for participating in this important initial discussion.

Looking forward to forming the subgroups and initiating detailed activities. Karen

#### Karen H. Tountas, PhD

Scientific Program Manager

## Foundation for the National Institutes of Health

(b) (6) fnih.org

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Sent: 2/17/2021 1:06:01 PM

Subject: FW: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021

Attachments: 02.17.21 ACTIV EC and Leadership Team Meeting 20210216\_vF.pdf; 02.17.21 ACTIV EC and Leadership Team

Meeting\_APPENDIX\_20210216\_vF.pdf; 2021-01-

 $14\_ACTIV\_Leadership\_Team\_and\_Executive\_Committee\_Meeting\_Summary\_vF.pdf$ 

From: Melencio, Che			On Behalf Of W	holley, David (FNIH	) [T]
Sent: Tuesday, Febru	or (NILL/NCATS) [6]	VI (6)	Pancel	Ctanhana	
<b>To</b> : Austin, Christoph < (b) (6 < (b) (6)	(NITINCATS) [E]	(0) (0)	(b) (6)	Cavalari Ma	roo
(b) (c)	Ciblo	r Tomas d	(b) (6)	Cavaleri, Ivia	is /NIII/OD/ (E)
(b) (c)	Consularmud	(b) (6)	(U) (U)	Collins, Franc	(P) (C)
(b) (6)	Corey, Larry <	(0) (0)	Cuip, iviiche	lile (NIH/OD) [E] <	(0) (0)
victoria Davey <	(D) (D)	Disbrow, Gary (	CS/ASPR/BARDA	(b) (b)	Dolsten, Mikael
(b) (6)	Embry, Al	an (NIH/NIAID)	E] < (b)	(6) Erbeid	ing, Emily (NIH/NIAID) [E]
(b) (6)	Erck, Stan <	(b) (6)	Fauci, Ant	nony (NIH/NIAID) [	E] < (b) (6)
					Gibbons, Gary
					James, Stephanie (FNIH) [
(b) (6)	Johnson, Robert (OS	/ASPR/BARDA)	(b) (6	) Krame	r, Lynn
(b) (6)	Lane, Cliff (N	IH/NIAID) [E] <	(b) (6)	Lepore, John	(b) (6)
Marks, Peter (FDA/CI	BER) < (b)	(6) N	lascola, John (NI	H/VRC) [E] <	(b) (6) Meeke
David < (b)					
(CDC/DDID/NCIRD/O	D) < (b) (6)	Pandya, Hites	sh <	(b) (6)	Pangalos, Mene
(b) (e	o) Pao	o, William <	(b) (6)	Parker, Ashle	y (NIH/OD) [E]
(b) (6)	Paul, Steve <	(b) (6)	Perlmutte	r, Roger <	(b) (6)
Plenge, Robert <	(b) (6)	Plump, Andy <	(b) (6)	) Rach	(b) (6) el Ramoni
(b) (6)	Reed, John <	(b) (6)	Reese, L	)avid < (b) (	6) Rouse, Doris
< (b) (6) Sar	itos, Michael (FNIH)	[T] < (b) (	6) Skovro	nsky, Daniel <	(b) (6)
Stein, Peter (FDA/CD	ER) < (b) (6	Sto	fels, Paul <	(b) (6) T	abak, Lawrence (NIH/OD)
[E] < (b) (6)	: Talley, M	ichael <	(b) (6)	Tsai, John <	(b) (6)
Vessey, Rupert <	(b) (6)	Virgin, Skip <	(b) (6) W	/holley, David (FNII	H) [T] < (b) (6)
					) Colvis,
Christine (NIH/NCATS	S) [E] < (b)	(6) De	srosiers, Betsy <	(b) (d	5) Eric
Hughes < (	(b) (6) Jai	nsen, Kathrin <	(b) (6)	Kurilla,	Michael (NIH/NCATS) [E]
(b) (6)	Lowy, Dougla	s(NCI) < (b	) (6) Read, :	Sarah (NIH/NIAID)	[E] < (b) (6)
Young, John <	(b) (6)				
Cc: Anderson, James	(NIH/OD) [E] <	(b) (6)	Burklow,	John (NIH/OD) [E]	< (b) (6)
Carluccio, Dana <	(b) (6)		Castillejos, Carlo	s < (b) (6)	Culp, Michelle
(NIH/OD) [E] <	(b) (6) F	NIH Central Acc	ount <	(b) (6)	Gadbois, Ellen (NIH/OD) [E
(b) (6)	Hallett, Adrien	ne (NIH/OD) [E]	(b) (6	) Lumso	len, Joanne (NIH/NCATS) [
(b) (6)	Myles, Rena	ate (NIH/OD) [E]	(b) (6)	Wolinetz,	Carrie (NIH/OD) [E]
(b) (6)	Adam, Stace		(b) (6)	Margaret Anderson	
(b) (6)	Appell,	Evan < (	(b) (6) C	hen, Helen <	(b) (6)
Connelly, Sarah <	(b) (6)	Dally, Nicolle	(b) (6)	Gonzalez,	Nina
(b) (6)	Hawk, Har	rison < (	b) (6) M	endelson, Jesse <	(b) (6)
Menetski, Joseph (FN	IIH) [T] < (b) (	<ol><li>Nasr,</li></ol>	Hana <	(b) (6) San	tos, Michael (FNIH) [T]
(b) (6)	Sorosa, Alex <	(b) (6)	Stratton, Be	njamin <	(b) (6) Tolman,
Brett < (b) (c	6) Wachtel	, Jonathan <	(b) (6)	Wholley, Dav	id (FNIH) [T]
(b) (6)			1000	245 14 550 A SAN	/ · · · · · / · · · · · · · · · · · · ·
(0) (0)	Burklow, John (NII	H/OD) [E] <	(b) (6)	Hallett, Adrienne	e (NIH/OD) [E]

< (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6)

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021

Dear ACTIV Leadership Team and meeting attendees:

France
France
France
Iapan
Iapan
Italy
Italy
Switzerland
Switzerland

Attached please find the slides for our meeting tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time. The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

Join Zoom Meeting https://fnih.zoom. (b)(6)Meeting ID: (b) (6) Passcode: (b) (6) One tap mobile (b) (6) US (Washington D.C) US (Chicago) Dial by your location (b) (6) US (Washington D.C) US (Chicago) US (New York) US (San Jose) US (San Jose) US (Tacoma) US (Houston) elgium elgium elgium elgium elgium elgium Canada Canada Canada Canada Canada Canada France

(b) (6) Switzerland
Switzerland
Switzerland
Switzerland
United Kingdom

Meeting ID: (b) (6)
Passcode: (b) (6)

Find your local number: <a href="https://fnih.zoom">https://fnih.zoom</a>. (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] Sent: 11/6/2020 6:01:02 PM To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Lowy, Douglas (NIH/NCI) [E] [ (b) (6) (b) (6) Arvin, Ann Beth Bell ( (b)(6)(b) (6) (b) (6) Cavaleri Marco | (b)(6)(b) (6) (b) (6) Greg Glenn | (b) (6) (b) (6) (b) (6) ]; Havnes, Barton | (b) (6) (b)(6)(b) (6) (b)(6)Marks, Peter (FDA/CBER) [ Mascola, John (NIH/VRC) [E] | (b)(6)(b)(6)Messonnier, Nancy (CDC/DDID/NCIRD/OD) | Nelson Michael | il]; (b) (6) (b)(6)Offit, Paul | Seals, Jonathan (OS/ASPR/BARDA) (b) (6) (b) (6) Tal Zaks (b)(6)1: (b) (6) (b) (6) (b)(6)CC: btolman | ]; Hopps, Markay | (b) (6) (b) (6) (b) (6) Kozlowski, Mary (NIH/NCI) [C] | ]; Johnson, Maureen (NIH/NCI) [E] (b) (6) Jeneffer Haynes | (b)(6)(b)(6)(b) (6) Austin, Sarah (NIH/NIAID) [E] (b) (6) (b) (6) (b) (6) Isabel Ramsey Parker. (b) (6) (b) (6) (b) (6) Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [ Erbelding, Emily (NIH/NIAID) [E] [ Dieffenbach, (b) (6) (b)(6)Carl (NIH/NIAID) [E] [ Qashu, Felicia (NIH/OD) [E] [ Culp, Michelle (b)(6)(b) (6) (NIH/OD) [E] [ Gadbois, Ellen (NIH/OD) [E] [ Wholley, David (FNIH) [T] (b)(6)(b) (6) (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Adam, Stacey (FNIH) [T] | (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] [ James, Stephanie (FNIH) [T] [ (b) (6) (b)(6)Desrosiers, Betsy Eric Hughes [ Kurilla, Michael (b)(6)(b)(6)(NIH/NCATS) [E] | Read, Sarah (NIH/NIAID) [E] [ Paul Gillard (b) (6) (b) (6) (b)(6)]; François P Roman [ (b) (6) Hamilton, Holli (OS/ASPR/BARDA) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA) (b)(6)Kathleen Neuzil | Martin, Stacey (b)(6)(b)(6)(CDC/DDID/NCEZID/DVBD) [ (b)(6)McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) | (b)(6)Schrag, Stephanie (CDC/DDID/NCIRD/DBD) | Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) (b)(6)Lindsey, Nicole (CDC/DDID/NCEZID/DVBD) (b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) [ 'Wachtel, Jonathan' (b)(6)]; Stratton, Benjamin (b) (6) Margaret Anderson | (b) (6) (b)(6)(b)(6)Bethany Stokes | Kathleen Callahan (b) (6) (b) (6) Molloy, Delia (DPH) [ Wood, Gretchen (NIH/OD) [E] (b)(6)(b)(6)Filip Dubovsky | (b) (6) (b) (6) Michael Watson (x) Antonio Lanzavecchia | Arvin, Ann (b) (6) (b) (6) (b)(6)Harris, Rebecca /SG | (b)(6)1; Vivek Shinde (b)(6)Cohen, Myron [ Criffield, Robin R. [ Marovich, Mary (b) (6) (b)(6)(NIH/NIAID) [E] | (b) (6) Young, John (b)(6)Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Jacqueline Miller (b)(6)Subject: **ACTIV Vaccines Working Group meeting** Location: https://fnih.zoom.us/j/ (b)(6)Start: 11/11/2020 6:00:00 PM End: 11/11/2020 7:00:00 PM

Show Time As: Busy

Required		(b) (6)	Lowy, Doug	las (NIH/NCI) [E];	(b) (6	)	Arvin, Ann; Beth Bell
Attendees:	(	(b) (6)	(b) (6)	Cavalo	eri Marco;	(b) (6)	
		(b) (6)	(	(b) (6)	Greg Glenn;	(b) (6	) Haynes,
	Barton	(b) (6)	(b) (6		Peter (FDA/CBER)	; Mascola, John	n (NIH/VRC) [E];
	Messo	nnier, Nancy (Cl	OC/DDID/NCIRD/O	D); Nelson Michae	l; Offit, Paul;	(b) (6)	Seals, Jonathan
	(OS/AS	PR/BARDA);	(b) (6)		(b) (6)	Tal Zaks	
Optional	Tolmar	, Brett;	(b) (6)	Hopps, Markay;	Kozlowski, Mary	(NIH/NCI) [C];	Johnson, Maureen
Attendees:	(NIH/N	CI) [E];	(b) (6)	Jeneffer Haynes;	(b) (6	)	(b) (6)
		(b) (6)	Austin, Sarah	(NIH/NIAID) [E];	(b) (6	)	Isabel Ramsey; Parker,
	Stepha [E]; Rea Modjan (CDC/E (CDC/E Thornb Margan Molloy Lanzav	nie (FNIH) [T]; C ad, Sarah (NIH/I rrad, Kayvon CIV DDID/NCEZID/DV DDID/NCIRD/DB Durg, Natalie (CE ret; ( , Delia (DPH); W	Colvis, Christine (N NIAID) [E]; Young, / USARMY MEDCO /BD); McNamara, D); Verani, Jennife DC/DDID/NCIRD/D' (b) (6) /ood, Gretchen (N	IH/NCATS) [E]; Des John; Paul Gillard; IM WRAIR (USA); K Lucy Alexandra (CD r R. (CDC/DDID/NC VD); Gonzalez, Nin (b) IH/OD) [E]; Filip Du	rosiers, Betsy; Hu François P Romar athleen Neuzil; N DC/DDID/NCIRD/I CIRD/DBD); Lindse a; Wachtel, Jonat (6) Ibovsky; Michael	aghes, Eric; Kur n; Hamilton, Ho Martin, Stacey DBD); Schrag, S ey, Nicole (CDC than; Stratton, Bethany Sto Watson (x); Jac	Karen (FNIH) [T]; James, illa, Michael (NIH/NCATS) olli (OS/ASPR/BARDA); stephanie /DDID/NCEZID/DVBD); Benjamin; Anderson, okes; Kathleen Callahan; equeline Miller; Antonio R.; Marovich, Mary

Michael Santos is inviting you to a scheduled Zoom meeting.

Topic: ACTIV Vaccines Working Group meeting

Time: Nov 11, 2020 01:00 PM Eastern Time (US and Canada)

## Join Zoom Meeting

https://fnih.zoom. (b) (6)

Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

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US (New York)

Dial by your location

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US (New York)
US (Chicago)
US (San Jose)
US (Tacoma)
US (Houston)
US (San Jose)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: https://fnih.zoom.u (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/16/2020 10:24:23 PM To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ Butterton, Joan ]; Collins, Sylva (FDA/CDER) (b) (6) (b) (6) [Sylva.Col Judy Currier De Claro, R. Angelo (FDA/CDER) (b) (6) (b) (6) Keith Gottesdiener (b)(6)Mark Eisner (b) (6) Eric Hughes | LaVange, Lisa M (b)(6)(b)(6)(b)(6)Elliott Levy [ Sandeep Menon | Amanda Peppercorn (b)(6)(b)(6)Proschan, Michael (NIH/NIAID) [E] | Read, Sarah (b) (6) (b) (6) (NIH/NIAID) [E] [ (b)(6)Amanda Peppercorn | ]; Price, Dionne (b) (6) (FDA/CDER) | Rubin, Daniel B. (FDA/CDER) | Shen, Yuan Li (b) (6) (b)(6)(FDA/CDER) | Farley, John (FDA/CDER) (b) (6) ]; Goff, David (b) (6) (NIH/NHLBI) [E] | (b) (6) Vincent, Michael | (b)(6)CC: Mary Biggs | Demarcus I (b)(6)Macone, Erin | (b)(6)(b)(6)Tountas, Karen (FNIH) [T] [ (b)(6)Wachtel, Jonathan (b)(6)Elizabeth Kim ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Rose Li Central Account Lucas Smalldon | Butcher, Tina (b) (6) (b) (6) (b) (6) Wholley, David (FNIH) [T] [ (b) (6) Melencio, Cheryl (FNIH) [T] Wung, Peter /US | (b) (6)

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #4

Attachments: ACTIV Therapeutics-Clinical MP Subgroup 21Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master

Protocol Sub-Group Meeting Agenda 04212020.pdf; D. Goff network capacity template 04202020.xlsx;

ACTIV Therapeutics-Clinical\_MP Sub-Group Meeting 3\_Key Takeaways\_04202020.pdf

Location: https://fnih.zoom. (b) (6)

Start: 4/21/2020 5:00:00 PM End: 4/21/2020 6:00:00 PM

Show Time As: Busy

Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo Attendees:

(FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David

(NIH/NHLBI) [E]; Vincent, Michael

Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees:

(NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl

(FNIH) [T]; Wung, Peter /US

Dear ACTIV TX-Clinical Master Protocol SG,

Please find attached the materials for today's call. Apologies for the slight delay in sending.

- Agenda
- 2. Slides for Discussion Updated Timelines for feedback and then questions to consider for the two master protocols to start deciding design.
- 3. Clinical Trial Network Survey the CTC WG would like any feedback we might have about other needed information.
- 4. High level update from yesterday

We look forward to speaking with you today.

```
Stacey
Join Zoom Meeting
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https://fnih.zoom.
Meeting ID:
                (b)(6)
Password: (b) (6)
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Meeting ID:
                 (b) (6)
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(b) (6)

Thanks,

Password: (b) (6)

Find your local number: https://fnih.zoom.us/u

Sent:

6/13/2020 5:15:39 PM

To:

Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]

Subject:

RE: Time sensitive: Making your ACTIV Participation Public

Attachments: Leadership \_ National Institutes of Health (NIH).pdf; 1-Draft\_NIH\_ACTIV\_Webpage\_Content 5.14.2020 w changes

updated editsLBAP.docx

Hi Renate,

Sparing FC's inbox and others.

With many thanks to Lauren for helping us with this. Please see edits attached and below - the alphabetizing of the names can be ignored as this is updated in the revised version you've provided.

A few minor edits:

- Co-chairs of the working groups should be identified
- Consistency with MD or M.D.
- Minor change to John Mellors

### Thanks,

Ashley

From: Myles, Renate (NIH/OD) [E] < (b)(6)

Sent: Friday, May 15, 2020 9:21 AM

To: Parker, Ashley (NIH/OD) [E] <

(b)(6)

Collins, Francis (NIH/OD) [E] <

(b)(6)

Cc: Allen-Gifford, Patrice (NIH/OD) [E] <

(b)(6)

Wooldridge, Shannon (NIH/OD) [E]

< (b) (6) Pollock, Rachel (NIH/OD) [E] <

(b) (6)

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,

Renate

From: Parker, Ashley (NIH/OD) [E] < (b)(6)

Sent: Friday, May 15, 2020 9:11 AM

To: Myles, Renate (NIH/OD) [E] <

(b) (6) : Collins, Francis (NIH/OD) [E] (b)(6)

Cc: Allen-Gifford, Patrice (NIH/OD) [E] <

(b)(6)

Wooldridge, Shannon (NIH/OD) [E]

: Pollock, Rachel (NIH/OD) [E]

(b)(6)

Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three - they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

#### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

(b) (6)

#### Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

(b) (6)

#### Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

(b) (6)

### Jay Grobler, Ph.D.

Director, Infectious Disease Biology

Merck & Co., Inc.

(b) (6)

#### Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory

(b) (6)

### David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

(b)(6)

### Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

(b) (6)

#### Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform Sanofi

(b) (6)

#### Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

(b) (6)

### Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

(b) (6)

### Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

(b)(6)

### Judith Currier, M.D.

Professor of Medicine University of California Los Angeles Division of Infectious Diseases Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

### John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

(b)(6)

#### Elliot Levy, M.D.

Senior Vice President, Global Development Amgen

(b) (6)

### Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi

(b) (6)

#### Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs Eli Lilly and Company

(b)(6)

### Peter Stein, M.D.

Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration (b) (6)

### Beth Bell, M.D., MPH

Clinical Professor, Global Health University of Washington

(b) (6)

### Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

(b)(6)



Senior Vice President and Head of Vaccine Research and Development

Pfizer

(b)(6)

### Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b) (6)

# Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

(b) (6)

### Jonathan Seals, Ph.D.

Director, Strategic Science and Technology

Biomedical Advanced Research and Development Authority

(b)(6)

From: Myles, Renate (NIH/OD) [E]

(b) (6)

Sent: Friday, May 15, 2020 7:53 AM

To: Collins, Francis (NIH/OD) [E]

(b) (6)

Cc: Allen-Gifford, Patrice (NIH/OD) [E]

(b) (6)

Parker, Ashley (NIH/OD) [E]

(b) (6)

: Wooldridge, Shannon (NIH/OD) [E]

(b) (6)

Pollock, Rachel (NIH/OD)

[E] < (b) (6)

Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashely sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

(b) (6)

### Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology Professor, Department of Microbiology and Immunology University of North Carolina, Gillings School of Global Public Health

### Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs U.S. Food and Drug Administration

### Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader RTI International

### Jay Grobler, Ph.D.

Director, Infectious Disease Biology Merck & Co., Inc.

## Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center The Jackson Laboratory

### David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit GlaxoSmithKline

## Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences United States Army Medical Research Institute of Infectious Diseases

### Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform Sanofi

### Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology Director and Chief Academic Officer Tulane University National Primate Research Center

### Frank Stegmeier, Ph.D.

Chief Scientific Officer KSQ Therapeutics

### Sylva Collins, Ph.D.

Director, Office of Biostatistics U.S. Food and Drug Administration

### Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b)(6)

## John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases Center for Drug Evaluation and Research U.S. Food and Drug Administration

(b) (6)

## Elliot Levy, M.D.

Senior Vice President, Global Development Amgen (b)(6)

### Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations Sanofi

(b) (6)

### Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs Eli Lilly and Company

(b)(6)

#### Peter Stein, M.D.

Director of Office of New Drugs Center for Drug Evaluation and Research U.S. Food and Drug Administration

(b)(6)

### Beth Bell, M.D., MPH

Clinical Professor, Global Health University of Washington

### Emilio Emini, Ph.D.

Director, TB & HIV Program
Bill & Melinda Gates Foundation

(b)(6)

## Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development Pfizer

(b)(6)

# Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow

Vir Biotechnology, Inc.

Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b)(6)

### Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention

(b)(6)

### Jonathan Seals, Ph.D.

Director, Strategic Science and Technology Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] < (b) (6)

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Myles, Renate (NIH/OD) [E] · Meltzer, Abbey (FNIH) [T] < (b) (6) >; Wholley, David

(FNIH) [T] < (b) (6)

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.

Thanks, Francis

Francis S. Collins, MD, PhD NIH Director From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 12/16/2020 4:11:58 PM To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsi4]; Bozzette, Sam (NIH/NCATS) [E] [ Butterton, Joan ]; De Claro, R. Angelo (FDA/CDER) (b)(6)(b)(6)Draghia-Akli, Ruxandra [ Gottesdiener, Keith (b)(6)(b)(6)(b)(6)]; Eric Hughes | Judy Currier (b) (6) Levy, Kim, Elizabeth [ LaVange, Lisa | (b)(6)(b) (6) (b) (6) Elliot [ Mellors, John W Menon, Sandeep [ (b)(6)(b)(6)(b)(6)]; Parker, Ashley (NIH/OD) [E] | (b)(6)Patel, Naimish | (b)(6)Peppercorn, Amanda | Proschan, Michael (b)(6)Poole, Mike (b)(6)(NIH/NIAID) [E] [ Read, Sarah (NIH/NIAID) [E] Santos, Michael (b)(6)(b)(6)Shen, Yuan Li (FDA/CDER) [ Stein, Peter (FDA/CDER) (FNIH) [T] [ (b)(6)(b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) (b)(6)Wholley, David (FNIH) [T] [ (b)(6)(b)(6)Collins, Sylva (FDA/CDER) | Amanda Peppercorn (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] | Koroshetz, Walter (b) (6) (b)(6)(NIH/NINDS) [E] [ Timothy Burgess [ Reineck, Lora (b)(6)(b) (6) Aggarwal, Neil (NIH/NHLBI) [E] | (NIH/NHLBI) [E] | (b) (6) (b)(6)Rosenberg, Yves (NIH/NHLBI) [E] [ Goff, David (NIH/NHLBI) [E] [ (b)(6)(b) (6) ]; Brown, Jeremy (NIH/NINDS) [E] (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [ Jacqueline Kirchner (b)(6)Beigel, John (NIH) [E] Phillips, L Revell CIV DTRA (b)(6)(b)(6)RD (USA) [ Petrovick, Martha - 0449 - MITLL I (b) (6) (b)(6)(b)(6)Sizemore, Christine (NIH/FIC) [E] [ (b)(6)Larry Tsai (b) (6) : Wung, Peter K [ Garner, Carl [garner\_ (b)(6)(b)(6)CC: Colvis, Christine (NIH/NCATS) [E] [ ]; Jansen, Kathrin [ (b)(6)(b)(6)Lowy, Douglas (NCI) Young, John ]; Biggs, Mary [ (b)(6)(b) (6) (b)(6)Butcher, Tina | Demarcus I Macone, Erin (b) (6) (b)(6)(b) (6) Melencio, Cheryl (FNIH) [T] [ (b)(6)Salathin, Carla (b) (6) ]; Menetski, Joseph (FNIH) [T] (b)(6)Dana Carluccio Rose Li Central Account [ ]; Lucas Smalldon (b) (6) (b)(6)]; Mollica, Linda /US (b)(6)(b) (6) Patterson, Amy (NIH/NHLBI) [E] Qashu, Felicia (NIH/OD) [E] [ (b)(6)(b) (6) (b) (6) 1; Rubin, Daniel B. (FDA/CDER) [ (b)(6)]; Marston, Hilary (NIH/NIAID) [E] Chen, Helen Q. [ Hoots, W. Keith (NIH/NHLBI) [E] (b)(6)Groesch, Mary (NIH/NHLBI) [E] [ Shipp, Allan (NIH/NHLBI) [E] (b)(6)(b)(6)Kindzelski, Andrei (NIH/NHLBI) [E] [ Hone, David M (Dave) CIV (b)(6)(b)(6)DTRA J9 (USA) [ Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b)(6)(b) (6) Walker, Paula (NIH/NINDS) [E] | (b) (6) Sorosa, Alex David Lumsden, Joanne (NIH/NCATS) [C] Lerner, Andrea (NIH/NIAID) (b) (6) (b) (6) [E] [ Embry, Alan (NIH/NIAID) [E] [ Dally, Nicolle (b)(6)(b)(6)(b) (6) Subject: **ACTIV Therapeutics-Clinical Working Group** Attachments: Untitled Attachment; Untitled Untitled Attachment; Untitled Attachment Location: https://fnih.zoom. (b) (6) Start: 1/7/2021 6:00:00 PM 1/7/2021 7:00:00 PM End:

Show Time As: Busy

Recurrence: Weekly

every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ( (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Optional Attendees: (b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K
Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina;
Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio;
Rose Li Central Account; Lucas Smalldon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD)
[E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen;
Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei
(NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA);
Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E];

Stacey Adam is inviting you to a scheduled Zoom meeting.

Embry, Alan (NIH/NIAID) [E]; Dally, Nicolle

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Join Zoom Meeting
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                                                (b) (6)
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Meeting IU:
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Passcode: (b) (6)
Find your local number: https://fnih.zoom.u:
                                                    (b)(6)
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/19/2020 10:12:59 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra Eisner, Mark | Gottesdiener, Keith (b) (6) (b) (6) (b) (6) Hughes, Eric | (b) (6) **Judy Currier** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth (b) (6) Levy, Elliot I LaVange, Lisa | (b) (6) Mellors, John W (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | Peppercorn, Amanda [ Poole, Mike (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn (b) (6) CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp) Subject: RE: Time Sensitive Request for Response from ACTIV Therapeutics-Clinical Working Group

Dear ACTIV Working Group Members,

To follow up on the request to publicly list your name associated with this ACTIV working group, we wanted to provide a bit more context.

As you may have heard on Friday, Dr. Francis Collins hosted a national news telebriefing with more than a dozen journalists from a variety of publications. Overall, the feedback was positive and some of the resulting articles can be found attached. Several reporters have subsequently asked for a list of those participating in ACTIV. We will not make this information public without the prior approval of the participants and their organizations. Therefore, we are checking with you as to whether you are willing to make your name, title, and company/institution available for this purpose. Should you prefer to withhold your name in this context, we will of course honor your wishes.

Again, please send your approval to Abbey Meltzer, FNIH's VP of Communications, at (b) (6) or reach out with any questions.

Best, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct:

(b) (6) | Mobile:

(b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Sunday, April 19, 2020 4:40 PM

Subject: Time Sensitive Request for Response from ACTIV Therapeutics-Clinical Working Group

Importance: High

Dear ACTIV Therapeutics-Clinical Working Group Members,

I hope this message finds you well. I am writing to seek your approval to publicly list your name in association with this ACTIV working group. A reporter has reached out to the FNIH asking for the names of the working group members, and we would like to point them to a listing of these names on the FNIH website, once you have provided clearance for this.

The FNIH's Vice President of Communications and Events, Abbey Meltzer, will be tracking these approvals, so please send your approval to her at If you have any questions, please do not hesitate to reach out to Abbey. (b) (6)

Best, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct:

(b) (6)

Mobile:

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852









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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS] Sent: 4/15/2020 6:08:29 PM To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc) Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups Attachments: Master list for ACTIV 041520.xlsx Francis – the following emails were missing from the list that went out, please see 8 emails listed below. Cheryl – attached is a revised master list (114 contacts) with names and emails which includes everyone. Disbrow, Gary (OS/ASPR/BARDA) < (b)(6)Kim, Elizabeth < (b) (6) Marston, Hilary (NIH/NIAID) [E] (b)(6)Paul, Steve < (b)(6)Payne, David < (b) (6) Plump, Andy (b) (6) >; Santos, Nancy (b) (6) Shen, Yuan Li (FDA/CDER) (b) (6) Thanks, Ashley From: Collins, Francis (NIH/OD) [E] < (b)(6)Sent: Wednesday, April 15, 2020 11:39 AM To: Melencio, Cheryl (FNIH) [T] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b)(6)Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one? From: Melencio, Cheryl (FNIH) [T] (b) (6) Sent: Wednesday, April 15, 2020 11:19 AM To: Parker, Ashley (NIH/OD) [E] <ashl Collins, Francis (NIH/OD) [E] <col (b) (6) (b)(6)Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bright, Rick < (b)(6)Collins, Francis (NIH/OD) [E] ; Disbrow, Gary (OS/ASPR/BARDA) >; Corey, Larry (b) (6) (b) (6) : Dolsten, Mikael Erbelding, Emily (NIH/NIAID) [E] (b)(6)(b)(6); Fauci, Anthony (NIH/NIAID) [E] <afauc ov>; Frankowski, David (b)(6)(b) (6) Hudson, Thomas < (b)(6)(b)(6)James, Stephanie (FNIH) Lane, Cliff (NIH/NIAID) [E] < [T] (b) (6) Klock, Kevin (FNIH) [T] (b) (6) (b)(6)Marks, Peter (FDA/CBER) />; Marston, Hilary (NIH/NIAID) [E] (b)(6)(b)(6)Mascola, John (b)(6)Meeker, David (b) (6) ; Menetski, Joseph (FNIH) [T] Pangalos, Mene <m ; Pao, William (b) (6) (b)(6)(b)(6)(b)(6)>; Perlmutter, Roger < Paul, Steve (b) (6) ; Plump, Andy ; Rasi, Guido < (b) (6) (b)(6)Reed, John (b)(6); Rouse,

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(b) (6) Santos, Michael (FNIH) [T] <
                                                   (b) (6) Skovronsky, Daniel
                          >; Stein, Peter (FDA/CDER)
                                                            (b) (6) Stoffels, Paul
          (b)(6)
                    Tabak, Lawrence (NIH/OD) [E] <
                                                                          Tsai, John
                                                           (b) (6)
        (b) (6)
                     >; Vessey, Rupert
                                                                            (b) (6)
                                                                                      >; Wholley, David
        (b)(6)
                                             (b) (6)
                                                           : Virgin, Skip <
                      >; Woodcock, Janet (FDA/CDER)
                (b) (6)
                                                                                      Young, John
(FNIH) [T] <
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                                                        (b) (6) Bascles, Lionel
          (b)(6)
                      ; Adam, Stacey (FNIH) [T] <
                         >; Cohen, Myron
                                                                      ; Corey, Larry
          (b)(6)
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Desrosiers, Betsy
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                                               Dickens, Jim (NIH/NCATS) [C] <
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                                   (b) (6) ; Goff, David (NIH/NHLBI) [E]
Doroshow, James (NIH/NCI) [E]
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                                                                                                ; Heaton,
        (b) (6)
                            ; King, James
                                                     (b) (6)
                                                                 ; Kurilla, Mike (b) (6)
                                                                                                >; Nayak,
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Seema (NIH/NIAID) [E]
                                         >; Parker, Ashley (NIH/OD) [E] <
                            (b) (6)
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                  >; Resnansky, Laura < (b) (6)
                                                           >; Srinivasan, Badhri
                              ; Stein, Peter (FDA/CDER)
                                                                              ; Tountas, Karen (FNIH) [T]
            (b) (6)
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      (b) (6)
                 >; Vincent, Mike
                                            (b) (6)
                                                             : Wachtel, Jonathan
                                                                                       (b)(6)
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Woodcock, Janet (FDA/CDER) <
                                       (b) (6)
                                                        Adam, Stacey (FNIH) [T] <
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                                                                                                : Bozzette,
                           (b) (6) ; Buchman, Tim (OS/ASPR/BARDA) (CTR)
Sam (NIH/NCATS) [E]
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Butterton, Joan
                         (b) (6) De Claro, R. Angelo (FDA/CDER) <
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Draghia-Akli, Ruxandra < (b) (6) Eisner, Mark < (b) (6)
                                                                                Gottesdiener, Keith
<
                            >; Hughes, Eric
                                                    (b) (6)
                                                                  >; Judy Currier
          (b) (6)
                         Kim, Elizabeth
                                                (b) (6) ; LaVange, Lisa <
                                                                                                 Levy, Elliot
           (b)(6)
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                    : Mellors, John <
                                                 Menon, Sandeep <
                                        (b) (6)
                                                                                                 : Parker,
       (b) (6)
                                                                                (b) (6)
Ashley (NIH/OD) [E]
                                         (Patel, Naimish
                                                                (b)(6)
                                                                                >; Peppercorn, Amanda
                          Poole, Mike <
                                                         (b) (6)
                                                                            Proschan, Michael
             (b) (6)
                        Read, Sarah <
                                                       Santos, Michael (FNIH) [T] <
                                                                                         (b)(6)
                                                                                                     Shen,
         (b)(6)
                                            (b) (6)
Yuan Li (FDA/CDER)
                                            (Stein, Peter (FDA/CDER) <
                                                                             (b) (6)
                                                                                          Adams, Peter
(OS/ASPR/BARDA)
                         (b) (6) Alvarez, Rosa < (b) (6)
                                                                              Anderson, Annaliesa
                               (Baric, Ralph (b
                                                              ; Carter, Kara <
                                                                                       (b) (6)
                            >; Deming, Damon (FDA/CDER)
                                                                                           Diamond,
Colvis, Christine
                                                                       (b) (6)
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Michael
                                 >; Duncan, Ken
                                                            (b) (6)
                                                                               ; Fernandes, Prabhavathi
                 (b) (6)
                            >; Gatto, Greg
                                                         Grobler, Jay <
                                                                                              Hewitt, Judith
           (b) (6)
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              ; Jonson, Samantha (NIH/NCATS) [E]
     (b) (6)
                                                          (b) (6)
                                                                          ; Lutz, Cat
                                                                                         (b) (6)
Menetski, Joseph (FNIH) [T]
                               (b) (6)
                                           >; Nestle, Frank
                                                                                  >; Ottinger, Liz
                                                                   (b) (6)
<ottingerea@mail.nih.gov>; Parker, Ashley (NIH/OD) [E] <
                                                           (b) (6)
                                                                         ; Payne, David
         (b)(6)
                        Rappaport, Jay
                                         (b) (6)
                                                            >; Stegmeier, Frank
                                                                                      (b)(6)
                                      Annunziato, Paula <
Young, John <
                      (b) (6)
                                                                     (b) (6)
                                                                                     Arvin, Ann
                                                                                       (b) (6)
                   >; Buchbinder, Susan
       (b)(6)
                                                  (b) (6)
                                                                   ; Corey, Larry
                    (b) (6) Emini, Emilio
                                                                                ; Hanon, Emmanuel
Davis, Mark <
                                                             (b)(6)
                        ; Haynes, Barton <
                                                                    Hotez, Peter <
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                                                                                                 Jansen,
           (b) (6)
                                                    (b) (6)
Kathrin <
                  (b) (6)
                                 ; Lanzavecchia, Antonio
                                                               (b) (6)
                                                                            h>; Lowy, Douglas (NIH/NCI) [E]
                  Marks, Peter (FDA/CBER) <
                                                                       Mascola, John (NIH/VRC) [E]
                                                       (b)(6)
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                     >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <
                                                                              : Offit, Paul
       (b) (6)
                                                                     (b) (6)
                     ; Parker, Ashley (NIH/OD) [E]
                                                                     ; Santos, Nancy
       (b) (6)
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Schuitemaker, Hanneke
                             (b) (6)
                                           Tartaglia, Jim <
                                                                  (b) (6)
                                                                                 ; Tolman, Brett
                          (b) (6) (b) (6)
       (b) (6)
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Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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Sent: 12/16/2020 2:40:18 PM

Subject: FW: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Attachments: 12.16 ACTIV EC and Leadership Team Meeting 20201215\_vF (003).pdf; 12.16 ACTIV EC and Leadership Team

Meeting\_APPENDIX\_20201215\_vF.pdf; 2020-11-19\_ACTIV\_Leadership\_Team\_Meeting\_Summary\_v3.pdf

From: Melencio, Cher Sent: Tuesday, Decen			On Beh	alf Of Wholl	ey, David (FNIH)	[T]	
To: Wholley, David (F			Austin Chris	topher (NIH)	/NCATS) [F] <	(b) (6)	
Bancel, Stephane <							ń
< (b) (6)							
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Subject: RE: ACTIV Le	adership Team Mee	eting, Tomor	row, Decem	ber 16, 2020	CORRECTION		

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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                            Meltzer, Abbey (FNIH) [T]
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Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020
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Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

**David Wholley** 

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/7/2020 8:56:23 PM To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes Read, Sarah (NIH/NIAID) [E] [ (b)(6)Ruxandra Draghia-Akli Mellors, John W Naimish Patel | Colvis, (b) (6) (b) (6) (b) (6) Christine (NIH/NCATS) [E] (b)(6)Young, John (b)(6)]; Stein, Peter (FDA/CDER) I Poole, Mike [ Buchman, Tim (b) (6) (b) (6) (OS/ASPR/BARDA) (CTR) [ Vincent, Michael I Keith (b) (6) (b)(6)Wung, Peter /US Gottesdiener | (b)(6)Elliott Levy | (b)(6)Koroshetz, Walter (NIH/NINDS) [E] [ Higgs, Elizabeth (b)(6)(b)(6)Carlos O Garner [garner Goff, David (NIH/NHLBI) [E] (NIH/NIAID) [E] [ (b) (6) (b)(6)CC: Elizabeth Kim (b) (6) ]; Menetski, Joseph (FNIH) [T] (b)(6)Alvarez, Rosa Maria (b)(6)]; Salathin, Carla [ (b)(6)(b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] Melencio, Chery (FNIH) [T] | Lucas Smalldon (b) (6) (b) (6) Walker, Paula (NIH/NINDS) [E] [ (b)(6)]; Ward, Jackie (b) (6) (NIH/NINDS) [E] (b)(6)Subject: ACTIV TX-Clinical Agent Prioritization Subgroup #9 Location: https://fnih.zoom.us/ (b) (6) Start: 5/12/2020 5:00:00 PM End: 5/12/2020 6:00:00 PM Show Time As: Busy Required Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine Attendees: (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E] Optional Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6) Attendees: Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b)(6)Stacey Adam is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnih.zoom.us/ (b)(6)Meeting ID: (b)(6)Password: (b) (6) One tap mobile (b)(6)US (New York) US (Germantown) Dial by your location (b) (6) US (New York) US (Germantown) US (Chicago) US (San Jose)

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(b) (6) Find your local number: https://fnih.zoom.

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] Sent: 6/30/2020 7:18:06 PM To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Lowy, Douglas (NIH/NCI) [E] [ (b)(6)(b) (6) Beth Bell ( (b)(6)Arvin, Ann (b) (6) (b) (6) Cavaleri Marco | (b)(6)(b) (6) (b) (6) Greg Glenn [ (b)(6)(b) (6) (b) (6) Havnes, Barton | (b) (6) (b)(6)(b) (6) (b)(6)Marks, Peter (FDA/CBER) [ Mascola, John (NIH/VRC) [E] [ (b)(6)(b)(6)Messonnier, Nancy (CDC/DDID/NCIRD/OD) | Nelson Michael | il]; (b) (6) (b)(6)Offit, Paul | Seals, Jonathan (OS/ASPR/BARDA) (b) (6) (b) (6) Tal Zaks (b)(6)1; (b) (6) (b) (6) (b)(6)CC: Tolman, Brett [ (b) (6) ]; (b)(6)Hopps, Markay (b)(6)]; Johnson, Maureen (NIH/NCI) [E] Kozlowski, Mary (NIH/NCI) [C] | (b)(6)Jeneffer Haynes | (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] (b) (6) (b) (6) (b) (6) (b)(6)(b) (6) Isabel Ramsev (b) (6) Parker. Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [ Qashu, Felicia (NIH/OD) [E] [ Culp, Michelle (b)(6)(b)(6)(NIH/OD) [E] [ Gadbois, Ellen (NIH/OD) [E] | Wholley, David (FNIH) [T] (b) (6) (b) (6) Menetski, Joseph (FNIH) [T] Melencio, Cheryl (FNIH) [T] | (b)(6)(b)(6)(b) (6) Adam, Stacey (FNIH) [T] | (b) (6) Tountas, Karen (FNIH) [T] [ (b) (6) James, Stephanie (FNIH) [T] [ (b) (6) Colvis, Christine (NIH/NCATS) [E] | (b)(6)Desrosiers, Betsy Hughes, Eric | Kurilla, Michael (b)(6)(b)(6)Read, Sarah (NIH/NIAID) [E] [ Paul Gillard (NIH/NCATS) [E] [ (b) (6) (b) (6) Hamilton, Holli (OS/ASPR/BARDA) | Modiarrad, Kayvon CIV (b)(6)(b) (6) USARMY MEDCOM WRAIR (USA) | Kathleen Neuzil I (b) (6) (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [ Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) (b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) | Gonzalez, Nina (b)(6)(b) (6) 'Wachtel, Jonathan' Stratton, Benjamin (b)(6)(b)(6)Anderson, Margaret [ (b)(6)(b) (6) (b) (6) (b)(6)Bethany Stokes | (b)(6)]; Kathleen Callahan Molloy, Delia (DPH) Arvin, Ann (b) (6) (b)(6)(b) (6) Vivek Shinde ]; Young, John | (b) (6) (b)(6)Subject: **ACTIV Vaccines Working Group meeting** Location: Webex: https://nih.webex. (b) (6) Start: 7/22/2020 5:30:00 PM End: 7/22/2020 6:30:00 PM Show Time As: Busy Required Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b)(6)Attendees: Arvin, Ann; Beth Bell ( (b)(6): Cavaleri Marco; (b)(6)(b) (6) Haynes, (b)(6)(b)(6)Greg Glenn; (b)(6)Barton; Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; (b) (6) (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b)(6)Seals, Jonathan (OS/ASPR/BARDA); (b)(6)Tal Zaks Optional Tolman, Brett; Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (b)(6)Attendees: (NIH/NCI) [E]; Jeneffer Haynes; (b)(6)(b)(6)

Austin, Sarah (NIH/NIAID) [E];

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Isabel Ramsey; Parker,

Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; Bethany Stokes; Kathleen Callahan; Molloy, (b) (6) (b)(6)Delia (DPH); Ann Arvin; Vivek Shinde -- Do not delete or change any of the following text. --Join Webex meeting Meeting password: (b)(6)Meeting number (access code): (b) (6) Join from a video system or application (b) (6) @nih.webex.com You can also dial (b) (6) and enter your meeting number. Tap to join from a mobile device (attendees only) Call-in toll number (US/Canada) Join by phone Call-in toll number (US/Canada) (b) (6) Global call-in numbers

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]

Sent: 11/13/2020 2:10:45 PM

To: Jessica (NIH/OD) Tucker [E] ( (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbefbffb5e52c31a4-tuckerjm]; Brodd, Lauren (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]

Subject: FW: Post-Acute Sequelae of COVID19 Workshop Dec 3-4

Attachments: Post-AcuteCOVIDWorkshopAgenda.pdf

## FYI. Maybe of broader OSP interest?

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CTR USARMY DOD JPEO CBRND (USA) < (b) (6) Freire, Maria (FNIH) [T] < (b) (6)

Elsaid, Olivia < (b) (6) Walker, Paula (NIH/NINDS) [E] < (b) (6) Bethany Stokes

< (b) (6) asorosa < (b) (6)

Subject: Post-Acute Sequelae of COVID19 Workshop Dec 3-4

Dear ACTIV TX-Clinical WG Members,

I am reaching out to let you know that NIAID with assistance from NHLBI and other NIH ICs is planning a workshop Dec 3-4 on Post-Acute Sequelae of COVID19 (i.e. Long COVID).

The agenda is attached and the website to register is here: <a href="https://cvent.me/MQAxOa">https://cvent.me/MQAxOa</a>

Given that this meeting will occur during our normal meeting time, we will be canceling our working group meeting on December 3<sup>rd</sup> to allow all those who wish to attend this conference to do so.

If you have any questions, please do not hesitate to reach out.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer

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To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsi4]; Bozzette, Sam (NIH/NCATS) [E] ]; Butterton, Joan De Claro, R. Angelo (FDA/CDER) (b) (6) (b)(6): Draghia-Akli, Ruxandra | (b)(6)Gottesdiener, Keith (b)(6)Eric Hughes | 1; Judy Currier (b)(6)(b)(6)Kim, Elizabeth | LaVange, Lisa | Mellors, (b) (6) (b)(6)(b) (6) Parker, Ashley (NIH/OD) [E] John W Menon, Sandeep [ (b)(6)(b) (6) Patel, Naimish [ Peppercorn, Amanda (b) (6) (b) (6) Poole, Mike [ Proschan, Michael (NIH/NIAID) (b) (6) (b)(6)[E] [ Read, Sarah (NIH/NIAID) [E] Santos, Michael (FNIH) [T] (b)(6)(b)(6)(b)(6)Shen, Yuan Li (FDA/CDER) [ (b)(6)Stein, Peter (FDA/CDER) Wholley, David (FNIH) [T] [ Buchman, Tim (OS/ASPR/BARDA) (CTR) (b)(6)(b)(6)1; Collins, Sylva (FDA/CDER) ]; Amanda Peppercorn (b)(6)(b)(6)Higgs, Elizabeth (NIH/NIAID) [E] [ (b)(6)Koroshetz, Walter (b)(6)(NIH/NINDS) [E] [ (b)(6)Timothy Burgess [ (b)(6)Reineck, Lora (NIH/NHLBI) [E] [ Aggarwal, Neil (NIH/NHLBI) [E] | Rosenberg, Yves (b) (6) (b)(6)Goff, David (NIH/NHLBI) [E] | (NIH/NHLBI) [E] | ]; Brown, Jeremy (b)(6)(b)(6)(NIH/NINDS) [E] | Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b)(6)Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [ Jacqueline Kirchner (b)(6)(b)(6)Beigel, John (NIH) [E] (b)(6)Phillips, L Revell CIV DTRA RD (USA) [ Petrovick, Martha - 0449 - MITLL | (b)(6)(b)(6)Sizemore, Christine (NIH/FIC) [E] | (b)(6)(b)(6)Larry Tsai Garner, Carl | (b)(6)Levy, Elliot | (b) (6) (b)(6)CC: Colvis, Christine (NIH/NCATS) [E] | ]; Jansen, Kathrin [ (b) (6) (b) (6) Lowy. Douglas (NCI) (b)(6)Young, John [ (b) (6) Biggs, Mary (b)(6)Butcher, Tina | Demarcus [ (b)(6)Macone, Erin (b)(6)Melencio, Cheryl (FNIH) [T] [ Salathin, Carla (b)(6)(b)(6)]; Menetski, Joseph (FNIH) [T] [ Dana Carluccio (b)(6)(b)(6)Rose Li Central Account | (b)(6)(b)(6)Lucas Smalldon (b)(6)1; (b) (6) Mollica, Linda /US Qashu, Felicia (NIH/OD) [E] Patterson, Amy (NIH/NHLBI) [E] (b)(6)(b)(6)Rubin, Daniel B. (FDA/CDER) | Marston, Hilary (NIH/NIAID) [E] (b) (6) (b)(6)Chen, Helen Q. Wung, Peter /US [ (b) (6) (b) (6) (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] [ ]; Groesch, Mary (NIH/NHLBI) [E] [ (b)(6)(b) (6) Shipp, Allan (NIH/NHLBI) [E] | Kindzelski, Andrei (NIH/NHLBI) [E] | (b)(6)(b) (6) Hone, David M (Dave) CIV DTRA J9 (USA) [ Reisler, Ronald B CTR USARMY DOD JPEO (b)(6)CBRND (USA) | (b) (6) Walker, Paula (NIH/NINDS) [E] | ]; Sorosa, Alex (b)(6)Lumsden, Joanne (NIH/NCATS) [C] [ David [ Lerner, Andrea (b) (6) (b)(6)(NIH/NIAID) [E] [ Embry, Alan (NIH/NIAID) [E] | Kelly Beazley (b) (6) (b)(6)(b)(6)

Start: 2/11/2021 6:00:00 PM End: 2/11/2021 7:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ( (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;

Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Levy, Elliot

Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina;

Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio;

Rose Li Central Account; Lucas Smalldon;

(b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD)

[E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen;

Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E];

Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea

(NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Kelly Beazley

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]

To:

CC:

[/o=ExchangeLabs/o	u=Exchange Administrative	e Group		
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(NIH/OD) [E] [/o=Exc	hangeLabs/ou=Exchange A	Administrative Group		
			030c31f6-shawcy]; Rodriguez, Robin D	
(b) (6)	Dave Frankowski [	(b) (6)	Baric, Toni C	
(b) (6)	Lowy, Doug	as (NIH/NCI) [E] [/o=Ex	changeLabs/ou=Exchange Administrative	
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(NIH/NIAID) [E] [/o=l	ExchangeLabs/ou=Exchang	e Administrative Group	0	
(FYDIBOHF23SPDLT),	/cn=Recipients/cn=5e032d	l0bc8554e8787e844a7	773295fe-florencewc]; Nancy Haigwood	
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(b) (6)	Gadbois, Ellen (NI	H/OD) [E] [/o=Exchange	eLabs/ou=Exchange Administrative Group	
(FYDIBOHF23SPDLT)	/cn=Recipients/cn=0243d1	.d6e6f248268d2edec56	66c26c2a-gadboisel]; Diamond, Michael	
(b) (6)	]; Gonzalez, Nina	(b) (6)		

Start: 6/10/2020 2:00:00 PM End: 6/10/2020 3:00:00 PM

Recurrence: (none)

Connelly, Sarah [ (b) (6) 12/2/2020 12:15:54 AM Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6) jrappaport@tulane.edu; ka (b) (6) (b) (6) jay (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-ihewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Parker, Ashley (NIH/OD) [E] (b)(6)(b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Tomas Cihlar Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [ (b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; KCLloyd@ucdavis.edu Diamond, Michael [ (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

From:

Sent:

To:

CC:

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan Prabhavathi (b) (6) Fernandes [ Rose Lil Dana Carluccio (b) (6) (b)(6)Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D (b) (6) Dave Frankowski | antoinette baric (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen (b)(6)RE: ACTIV Preclinical full working group

Subject:

Attachments: ACTIV\_Preclinical\_Viral Mutation and Prediction of Escape\_12012020\_v1.pptx

Hi All,

Apologies for the multiple emails, ahead of our meeting tomorrow, the preclinical team has refined the slides that will guide our discussion on ongoing viral sequence tracking and testing efforts (attached).

Prior to our meeting, please take a moment to review these topics and be ready to share any thoughts you may have. We look forward to continuing the discussions and appreciate the time and effort you all have put towards this subject to date.

Best regards, Sarah

Sarah Connelly, PhD Deloitte Consulting, LLP Tel/Direct: (b) (6)

www.deloitxe.com

From: Connelly, Sarah

Sent: Tuesday, December 1, 2020 4:12 PM

To: N	lenetski, Joseph	(FNIH) [T] <	(b) (6)		(b) (6)	Hild, Sher	i (NIH/OD) [E]
<	(b) (6)	(b) (6)		(b) (6)		(b)	(6)
	(b) (6)	(b)	(6)	(b) (6)	Baric, Ralph	1 < (b)	(6)
	(b) (6)	Ottinge	r, Elizabeth (1	VIH/NCATS [E]	<	(b) (6)	Colvis, Christine
(NIH/	NCATS) [E] <	(b) (6)	Hewitt,	Judith (NIH/N	A D) [E] <	(b) (6)	Deming, Damon
(FDA)	/CDER) <	(b) (6)		(b) (6)		(b) (6)	(b) (6)

, Ashley (NIH/OD)	) [E] <	(b)	(6)	Coll	ins, Franc	is (NIH/C	)D) [E] <	(b) (6)		
(b) (6)		Adams	s, Peter (	OS/ASPF	R/BARDA)	<	(b) (6)	Rao	, Srinivas	
(b) (6)	Qash	nu, Felici	a (NIH/C	D) [E] <	(1	b) (6)	Toma	as Cihlar		
(b) (6)	Pitt	, Margar	et L CIV	USARMY	MEDCON	M USAMI	RIID (USA) <		(b) (6)	
ieri, Antonello (N	IH/NHLBI	) [E] <		(b) (6)		Charette	, Marc (NIF	I/NHLBI) [E]		
								(b) (6)	Lu	msden,
(NIH/NCATS) [C]	<	(b) (6)	)		(b) (6)					
mond, Michael <	(	(b) (6)	ν	Vholley,	David (FN	IIH) [T] <	(b) (	6) A	ustin, Chr	istopher
ICATS) [E] <	(b) (6)		Melenci	o, Chery	I (FNIH) [1	Γ] <	(b) (6)	Desro	osiers, Bets	sy
(b) (6)		Eric	Hughes	<	(b) (6)	)	Jansen,	Kathrin		
(b) (6) Read,	, Sarah (N	IH/NIAIC	) [E] <	(b	) (6)	Tou	ntas, Karen	(FNIH) [T] <	(b)	(6)
(b) (6)	Alvarez, R	losa Mar	ia <	(b)	(6)	Kim	, Elizabeth	< (b	) (6)	Tolman
(b) (6)	V	Wachtel,	Jonatha	n <	(b) (e	6)	Prabha	avathi Ferna	indes	
(b) (6)		Rose	Li <	(1	b) (6)		Dana Carlu	ccio		
(b) (6)		L	agos, En	rique (N	IH/NCATS	s) [E] <	(b) (	6)	Jonson, S	amantha
ICATS) [E] <	(b) (	6)	Go	nzalez, N	lina <	J)	o) (6)	Simor	ı, Dina (NII	H/OD) [C]
(b) (6)	Burrus-Sh	naw, Cyn	di (NIH/	OD) [E] <		(b) (6)		Rodriguez	, Robin D	
(b) (6)	Dave Fra	ankowsk	i <		(b) (6)		В	Baric, Toni C	100	
(b) (6)		Lowy,	Douglas	(NIH/NO	(I) [E] <	(b)	(6)	Florence, (	Clint (NIH/	NIAID) [E]
is, Ellen (NIH/OD)	[E] <	(b) (	(6)	Ande	erson, Jan	nes (NIH)	OD) [E] <	(b	) (6)	
Harrison <	(b) (6)	J	Mason, S	Stephen •	<	(b) (6	)			
(b) (6)			(b	) (6)						
	(b) (6) (b) (6) (b) (6) ieri, Antonello (N (b) (6) (NIH/NCATS) [C] mond, Michael < ICATS) [E] < (b) (6)	(b) (6) (b) (6) (b) (6) (b) (6) Pitt ieri, Antonello (NIH/NHLBI) (b) (6) Fessel (NIH/NCATS) [C] < mond, Michael < (CATS) [E] < (b) (6) (b) (6) (b) (6) (b) (6) Read, Sarah (N Michael (FNIH) [T] < (b) (6) Alvarez, R (b) (6) (b) (6) (b) (6) (cats) [E] < (b) (6) (do (do (b) (6) (do	(b) (6) Adams (b) (6) Qashu, Felici (b) (6) Pitt, Margar ieri, Antonello (NIH/NHLBI) [E] < (b) (6) Fessel, Josh (Nith (NIH/NCATS) [C] < (b) (6) (c) (MIH/NCATS) [C] < (b) (6) (d) (d) (e) (f) (f) (f) (f) (f) (f) (f) (f) (f) (f	(b) (6)	(b) (6)	(b) (6)	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group Members,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
Preclinical WG Strategic Objectives - Updates	20 mins	Jae Menetski John Young Christine Colvis
Discuss Viral Mutation and Prediction of Essape	20 roles	ioe Menetski Iohn Yaung Christine Caivis
Discuss Subgroup updates  Of Preclinical prioritization  Of In vivo strategy  Of Field Guides  Of Viral Stocks  Otal portal implementation	10 mins	John Young Nancy Haigwood Cat Lutz Isis Kanevsky Clint Florence Sam Jonson
Discuss Small Animal Models and NHP Field Guides	10 mins	Nancy Haigwood Cat Lutz Isis Kanevsky

Looking forward to talking to everyone tomorrow!

All the best, Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
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----Original Appointment----
                                        (b)(6)
From: Menetski, Joseph (FNIH) [T]
Sent: Tuesday, April 14, 2020 6:43 PM
To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];
                                                                 (b)(6)
                                                                                          (b) (6)
                                                     (b) (6)
                   (b) (6)
                                         Baric, Ralph;
                                                                  (b) (6)
                                                                                    ; Ottinger, Elizabeth (NIH/NCATS
[E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER);
                                                                        ; Parker, Ashley (NIH/OD) [E]; Collins, Francis
                                                Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD)
(NIH/OD)[E];
                            (b)(6)
[E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E];
Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E];
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine
(NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI);
Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James,
Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes;
Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina
(NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas
(NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E];
Anderson, James (NIH/OD) [E]; Hawk, Harrison; Diamond, Michael; Mason, Stephen;
                                         Connelly, Sarah
                 (b)(6)
Subject: ACTIV Preclinical full working group
When: Wednesday, November 11, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: https://fnih.zoom.us/
                                                         (b)(6)
Changing time for preclinical WG
Joseph Menetski is inviting you to a scheduled Zoom meeting.
Join Zoom Meeting
https://fnih.zoom.us/j/
                                                  (b)(6)
Meeting ID:
                (b)(6)
Passcode: (b) (6)
One tap mobile
                   (b) (6)
                                               US (Germantown)
                                               US (Chicago)
Dial by your location
          (b)(6)
                     US (Germantown)
                     US (Chicago)
                     US (New York)
                     JS (San Jose)
                     US (San Jose)
                     US (Tacoma)
                     US (Houston)
Meeting ID:
                (b) (6)
Passcode: (b) (6)
Find your local number: https://fnih.zoom.
                                               (b)(6)
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v.E.1

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/13/2020 7:23:25 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra Eisner, Mark | (b) (6) Gottesdiener, Keith (b) (6) (b)(6)Hughes, Eric | (b) (6) **Judy Currier** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth Levy, Elliot I LaVange, Lisa (b) (6) (b) (6) Mellors, John W (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) ]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | Peppercorn, Amanda | Poole, Mike (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy ]; Jansen, Kathrin [ Kurilla, Michael (NIH/NCATS) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John ]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Biggs, Mary (b) (6) Butcher, Tina [ (b)(6)Demarcus | Macone, (b) (6) Erin [ (b)(6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla ]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth ]; Alvarez, Wachtel, Jonathan [ Tolman, Brett | (b) (6) (b) (6) (b) (6) Rosa (b) (6) ]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d] Follow-up from 1st Meeting of COVID PPP Therapeutics-Clinical Working Group - RAPID RESPONSE REQUESTED Subject: Attachments: berlin definition.pdf; gattinoni.pdf; ARDS history.pdf; ashbaugh and petty.pdf; Tenney Remers.pdf

COLL0000022465- (b) (6)

Dear ACTIV Therapeutics-Clinical WG,

Thank you all for a very productive discussion today. We appreciate all of you taking the time to join the meeting.

As discussed on the call today, I am reaching out to ask for volunteers for each of the two main sub-groups for our WG:

- 1. Agent Prioritization Process, Criteria, and Initial Agent List
- 2. Development of COVID Master Protocols

Please send me your availability to participate and your preference for which sub-group you would like to join. In addition, please send your preferred time windows or any restricted times over the next two days. Please send me this information by no later than 10 pm US ET today if you can. This will allow us to plan the meetings rapidly for Tuesday and Wednesday.

We will be working to get together agendas and will share them as they come together.

In addition to sending the information above, Tim Buchman from BARDA asked me to share the attached materials and the thoughts below for consideration on our use of the ARDS terminology.

## A Remark on Terminology: "ARDS" as an expression of COVID-19

Contemporary respiratory distress syndromes were unknown until the 1960s. Prior to the invention and diffusion of mechanical ventilators following the polio epidemics of the 1950s, patients simply succumbed to severe pneumonia.

In 1967, David Ashbaugh, Tom Petty and others reported a case series of a dozen patients who experienced severe respiratory illness with chest radiographs similar to what would observed in congestive heart failure but without the heart failure (pdf attached). The lungs simply leaked fluid.

The history of that report is summarized by Levine (one of the authors of the 1967 report) and is also attached.

Pertinent to the next half century of ARDS are the following:

- (a) "ARDS" was recognized as a final common pathway to diverse insults including (but not limited to) trauma, pancreatitis, pneumonia, and anatomically distant sepsis;
- (b) development of a standard supportive strategy namely "lung protective, low-tidal volume ventilation" that emerged from ARDSNET (see <a href="https://www.nejm.org/doi/full/10.1056/NEJM200005043421801">https://www.nejm.org/doi/full/10.1056/NEJM200005043421801</a>) but in fact simply reflected normal tidal volumes across all mammals, see figure 1 in the Tenney and Remmers 1963 paper, pdf attached.
- (c) a contemporary definition of ARDS that focuses almost exclusively on the extent of hypoxemia without attention to the defect in diffusion of oxygen across the alveolar-capillary membrane (the Berlin criteria, pdf attached).

Thus until 2020, ARDS accumulated underlying pathogeneses. As a consequence, treatment focused on "greatest good for greatest number". Whilst address of the underlying cause has always been part of ARDS treatment, the ventilator support regimen has been largely "one size fits most".

SARS-CoV-2 has changed the landscape. A single pathogen has affected populations of diverse heritable and acquired underlying pulmonary conditions. The pathophysiologic responses to the pathogen are partitioning into several endotypes. This has prompted both experts and pundits to call for a revision of the "one size fits most" into more tailored approaches. See the Gattinoni pdf published a couple of weeks ago in the ATS journal (pdf attached.)

There is a manuscript from John Marini and Gattinoni that will run in one of the journals I edit in the near future focusing on how ventilators injure vulnerable lungs. Luciano Gattinoni has separately contacted one of my Associate Editors to write a piece for the other journal that I edit. Suffice it to say that the conversation about partitioning treatment into approaches that reflect the expression of COVID-19 could well be part of the presentation.

I share all of the above information simply to highlight the fact that convolving the pulmonary injury consequent to SARS-CoV-2 with the term "ARDS" brings a half-century of knowledge—and also of baggage—to the therapeutics

conversation. Perhaps we should be as careful and specific in the terms we choose to describe the pulmonary injury as we should be in testing candidate therapies.

Our choice of words, like our choice of drugs, matters.

Tim

Timothy G. Buchman, PhD, MD Senior Advisor IPA to the DRIVe (Division of Research, Innovation and Ventures) Biomedical Advanced Research and Development Authority (BARDA) Office of Assistant Secretary for Preparedness and Response (ASPR) U.S. Department of Health and Human Services (HHS)

Thank you all in advance for your timely responses.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships

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From: Plenge, Robert [ (b) (6)

Sent: 7/29/2020 11:33:01 AM

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data (<u>here</u>, <u>here</u>, <u>here</u>, <u>here</u>), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

From:	"Melencio, Ch	eryl (FNIH) [T]" <	(b) (6)	on behalf of	"Wholley, Dav	id (FNIH) [T]"
<	(b) (6)					
Date:	Tuesday, July 2	8, 2020 at 10:55 PM				
To: "At	ustin, Christop	her (NIH/NCATS) [E]"	< (b) (6)	"Bar	ncel, Stephane'	1
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[E]" <	(b) (6)	"Corey, Larry"	(b) (6)	"Cul	lp, Michelle (N	IH/OD) [E]"
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Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference
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### [Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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Meltzer, Abbey (FNIH)	[T] [ (b)	(6)	Regan, Donna M		(b) (6)		Lucas Sma	lldon
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Location: https://fnih.zoom. (b) (6)

**Start**: 9/23/2020 1:00:00 PM **End**: 9/23/2020 2:00:00 PM

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Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Bugin, Kevin (FDA/CDER) Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Caulfied, Anita; Coan, Amanda; Conrad,

Optional Attendees:

Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; EdI, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Regan, Donna M; Hamilton, Nancy; Lucas Smalldon; Alvarez, Rosa Maria; Gonzalez, Nina; Appell, Evan; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Hawk, Harrison; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Dana Carluccio; Lowy, Douglas (NIH/NCI) [E]; John Lepore; Huang, Grant

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent: 5/11/2020 4:45:30 PM

To: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Melencio, Cheryl (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl – should I forward the invite or would you prefer to add on your end?

Thank you, Ashley

CC:

From: Wood, Gretchen (NIH/OD) [E] < (b) (6) Sent: Monday, May 11, 2020 9:23 AM To: Collins, Francis (NIH/OD) [E] < Fauci, Anthony (NIH/NIAID) [E] < Gibbons, (b) (6) (b)(6)Stoffels, Paul < PSt Gary (NIH/NHLBI) [E] < (b) (6) (b)(6)Pao, William < (b)(6)Dolsten, Mikael < (b)(6)Colvis, Christine (NIH/NCATS) [E] Desrosiers, Betsy < Hughes, Eric (b)(6)(b)(6)Jansen, Kathrin < Kurilla, Michael (NIH/NCATS) [E] (b)(6)(b)(6)Read, Sarah (NIH/NIAID) [E] < Lowy, Douglas (NCI) < (b)(6)(b)(6)(b) (6) Young, John < Cc: Wholley, David (FNIH) [T] < Menetski, Joseph (FNIH) [T] < Adam, Stacey (b) (6) (b) (6) Santos, Michael (FNIH) [T] (FNIH) [T] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Freire, Maria (FNIH) [T] < Tabak, Lawrence (NIH/OD) [E] (b)(6)Lane, Cliff (NIH/NIAID) [E] < Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b)(6)Anderson, James (NIH/OD) [E] < Austin, Christopher (NIH/NCATS) (b) (6) Melencio, Cheryl (FNIH) [T] < [E] < (b)(6)(b) (6) Subject: Re: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

Gretchen

From: Francis Collins < (b) (6) Date: Saturday, May 9, 2020 at 1:07 PM To: Francis Collins >, Anthony Fauci "Gibbons, Gary (NIH/NHLBI) (b)(6)(b)(6)[E]" < (b)(6)(b)(6)Gretchen Wood < (b)(6)"Pao, William" < (b)(6)(b)(6)"Desrosiers, (b)(6)>, "Colvis, Christine (NIH/NCATS) [E]" (b)(6)

Betsy"		(b) (6)	"Hughes, E	Eric" <	(b	) (6)	"Jansen, Kathrin"
		(b) "Kurilla	, Michael (NIH/N	CATS) [E]"		(b) (6)	, "Lowy, Douglas
(NCI)" <	(b) (6)	"Read, Sarah	(NIH/NIAID) [E]"	<	(b) (6)	"Young	, John"
	(b) (6)						
Cc: Dav	id Wholley <	(b) (6)	"Menetski, Jo	seph (FNII	H) [T]"	(b) (6)	, "Adam, Stacey
(FNIH) [	[T]" < $(b)$	(6) "Tount	as, Karen (FNIH)	[T]" <	(b) (6)	"Santo	os, Michael (FNIH) [T]"
<	(b) (6)	Maria Freire <	(b) (6)	"Tabak, I	awrence	(NIH/OD) [E]"	
<	(b) (6)	"Lane, Cli	ff (NIH/NIAID) [E]	]" <	(b) (6)	, Ashley	Parker
<	(b) (6)	James Ande	erson <	(b) (6)		"Austin, Christ	topher (NIH/NCATS)
[E]" <	(b) (6)	, "Melenci	io, Cheryl (FNIH)	[T]" <	(b) (6)	>, Greto	chen Wood
<	(b) (6)						

Subject: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. There are also concerns about how we should best communicate across our partnership and coordinate with the many parallel (and in some cases conflicting) efforts that have emerged elsewhere—including among our own ACTIV members.

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/28/2020 8:32:48 PM To: Eric Hughes | (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [ Colvis, (b) (6) Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John ]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ Keith Gottesdiener [ Elliott Levy (b) (6) (b) (6) (b)(6)Wung, Peter /US | ]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs] Elizabeth Kim [ CC: ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Salathin, Carla | (b)(6)(b)(6)(b)(6)Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon (b)(6)Subject: ACTIV Therapeutics-Clinical Agent Prioritization Subgroup Meeting #5 Location: https://fnih.zoom.us, (b)(6)4/30/2020 7:00:00 PM Start: End: 4/30/2020 8:00:00 PM Show Time As: Tentative Required Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine Attendees: (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E] Optional Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b)(6)(b) (6) Attendees: Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon

Dear TX-Clinical APSG,

I had my days incorrect. This meeting was supposed to be tomorrow (Wednesday). I don'think this is the right timing, so I am moving it to Thurdsay and scheduling another call on Friday per our discussion.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/23/2020 5:17:02 PM To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ Butterton, Joan Judy Currier (b)(6)(b)(6)Eric Hughes | LaVange, Lisa M [ (b) (6) (b)(6)(b)(6)Read, Sarah (NIH/NIAID) [E] [ (b)(6)Karen Lynn Price [ Higgs, Elizabeth (b) (6) (NIH/NIAID) [E] [ Woodcock, Janet (FDA/CDER) Stein, Peter (b) (6) (b)(6)(FDA/CDER) I Carlos O Garner [ Bugin, Kevin (FDA/CDER) (b) (6) (b) (6) (b)(6)Marks, Gilbert (OS/ASPR/BARDA) (CTR) Farley, John (b) (6) (FDA/CDER) Jens Lundgren (b)(6)(b)(6)CC: Demarcus | Wachtel, Jonathan ]; Tountas, Karen (FNIH) [T] [ (b)(6)(b) (6) Elizabeth Kim I Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. Salathin, Carla (b)(6)Subject: **ACTIV** mAb Steering Committee Meeting Attachments: ACTIV TX-Clinical mAb Steering Committee Meeting 20200529.pdf Location: https://fnih.zoom.us, (b) (6) Start: 5/29/2020 6:00:00 PM End: 5/29/2020 7:00:00 PM Show Time As: Busy Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Attendees: Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER); Jens Lundgren Optional Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Attendees: Salathin, Carla Dear mAb Steering Committee, Please find attached the proposed agenda and slides for tomorrow. Please let us know if we need to add anything else to the agenda. Thanks, Stacey Join Zoom Meeting https://fnih.zoom. (b)(6)Meeting ID: (b) (6) Password: (b) (6) One tap mobile (b)(6)US (Germantown) US (Chicago) Dial by your location (b)(6)US (Germantown)

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Find your local number: <a href="https://fnih.zoom.us/">https://fnih.zoom.us/</a> (b) (6)

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP] Sent: 4/17/2020 1:11:38 PM To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp); (b)(6)(b)(6)(b)(6)(b)(6)Baric, Ralph [/o=ExchangeLabs/ou=Exchange (b) (6) (b)(6)(b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email; Ottinger, Elizabeth (NIH/NCATS [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-ihewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Srinivas.Rao@sanofi.com; Alvarez, Rosa Maria (b)(6)CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy ]; Hughes, Eric | Jansen, Kathrin (b) (6) (b)(6)Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth Tolman, Brett | Wachtel, Jonathan (b)(6)(b) (6) (b) (6) Prabhavathi Fernandes | (b)(6)Diamond, Michael [ (b) (6) Rose Li Dana Carluccio | Lagos, Enrique (NIH/NCATS) (b)(6)(b)(6)[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses] Subject: RE: COVID Preclinical Working group Meeting #2 PRECLINICAL Working Group FNIH\_Meeting 2\_0417\_vF4.pdf; 20200416\_PRECLINICAL Working Group\_Animal Attachments: Models\_Actions and observations \_d3.docx; Inventory Template columns for WG review\_4 16 2020.xlsx; In vitro Subteam notes and actions 4 16 d4.docx

COLL0000011074-2517524

Hi all, Please find attached a few materials for our discussion today: Slides for our discussion today 1. 2. Notes from the Animal Model Subgroup Notes from the In Vitro Assay Subgroup Framework for the preclinical data inventory (including data fields for the Preclinical compound 3. list, Animal Model list, In vitro Assay List and BSL 3/4 Facilities List) Please let us know if you have any modifications to the data fields to be included in the inventory For logistic purposes, if you plan to call into the meeting with phone only, could you please send me your telephone number prior to the meeting. Having you number will allow me to keep track of who is attending the meetings. Looking forward to our discussion at 11am ET. Sincerely, ----Original Appointment----From: Menetski, Joseph (FNIH) [T] (b) (6) Sent: Sunday, April 12, 2020 12:50 PM To: Menetski, Joseph (FNIH) [T]: (b)(6)(b) (6) Annaliesa.Anderson@ofizer.com: (b) (6) (b)(6)(b)(6)kara. (b) (6) Baric, Ralph; (b) (6)
Christine (NIH/NCATS) [E]: Hewitt. Judith (NIH/NIAID) (b) (6) Ottinger, Elizabeth (NIH/NCATS | El: Colvis. (FDA/CDER): (b) [E]; Deming, Damon (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) Subject: COVID Preclinical Working group Meeting #2
When: Friday, April 17. 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: https://zoom. (b)(6) Saving time on the calendar. Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting (b) (6) https://zoom.us <https://zoom.u Meeting ID: (b) (6) Password: (b) (6) One tap mobile US (Chicago) (b) (6) US (New York)

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US (San Jose)

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent: 4/19/2020 6:39:15 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]

Subject: FW: URGENT: Invitation to join the ACTIV Vaccines Working Group

FYI we have heard back from Stephane Bancel: Moderna will be sending their CMO, Tal Zaks (who is leading CoV2 vaccine development), to join the Vaccines call tomorrow. He's been sent the invite and has acknowledged receipt. Thanks for your help, Francis.

From:

Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]

Sent:

10/16/2020 8:50:45 PM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject:

FW: 1st ACTIV-1 patient has been randomized

Flag:

Follow up

### Francis,

Thought you'd enjoy seeing this, came to me just as our Livestream ended. And note it's WashU, where the trial PI (Bill Powderly) is, in case that's useful for Mr. Blunt. Chris

		NIH/NCATS) [E] <	(b) (6)				
		16, 2020 4:48 PM					
<b>Го</b> : Во	ucher, Cynthia (	NIH/NCATS) [E] <	(b) (6)	Atkinson,	Jane (NIH/NCA	ATS) [E]	
<	(b) (6)	Chang, Soju (NIH/N	CATS) [E] <	(b) (6)	(b) (	(6)	
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3haru	cha_David' <	(b) (6)	'Fergusor	n_William' <	(b) (	(6)	Eric Hugh
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	(b) (6)	Austin, Christo	pher (NIH/NCATS	S) [E] <	(b) (6)	Collins, Fr	ancis (NIH/OD) [
	(b) (6)	Woodcock, Janet (FDA	/CDER) <	(b) (6)	Mas	on, Robin	(OS/ASPR/BARDA
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c: 'M	ontgomery, Step	ohanie' <	(b) (6)	O'Sulliva	n_Alexandra		
	(b) (6)	Stock,	Thomas (HHS/IO	S) < (b)	(6)	Neta Nels	on
	(b) (6)	Butler, Sandy <	(b) (6)	Daniel Ben	jamin Jr, M.D.,	Ph.D.	
	(b) (6)	Theresa Jasior	(b)	(6) N	Iolina, Daniel <		(b) (6)
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Subject: 1st ACTIV-1 patient has been randomized

# Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all! Sam B

Sam Bozzette. MD, PhD Chief Medical Officer Immediate Office of the Director National Center for Advancing Translational Sciences National Institutes of Health

6701 Democracy Blvd., Room 926 Bethesda, MD 20892 (Use ZIP code 20817 for overnight mail or courier) (b) (6)

Phone: (b) (6) E-mail:

NIH NCATS: COLLABORATE, INNOVATE, ACCELERATE.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent: 10/20/2020 8:55:08 PM

To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]

Subject: RE: ACTIV Leadership Team Meeting October 21, 2020

Slight typo in the salutation calling this the AMP Leadership Team. Made me wonder where I was for a minute. ③

	: Melencio, Cheryl			On Behal	f Of Wholle	ey, David (FNI	H) [T]	
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Conn	(b) (6) elly, Sarah <	(b) (6)	Gonzalez, N e <	ina <	(b) (6)	) l netski, Joseph	ławk, Harris	

Tountas, Karen (FNIH) [T] Benjamin < (b) (6) btolman < (b)(6)Wholley, David (FNIH) [T] < Wachtel, Jonathan < (b)(6)(b) (6) (b)(6)

Subject: ACTIV Leadership Team Meeting October 21, 2020

Importance: High

Dear AMP Leadership Team and meeting attendees:

Attached please find the slides for our meeting tomorrow morning, Wednesday October 21, from 9:15 - 10:15 AM Eastern U.S. Time. We will be focusing a good part of the call on trial accrual challenges discussed during our ACTIV Executive Committee call on October 7. The minutes from that meeting as well as those from our last Leadership Team call on September 23 are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Find your local number: https://fnih.zoom. (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From:

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent:

2/13/2021 4:17:15 PM

To:

(b) (6)

CC:

Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lane, Cliff (NIH/NIAID) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wood, Gretchen (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Barasch, Kimberly

(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia

(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]

Subject:

RE: [EXTERNAL] a few follow ups

Hi

(b) (6)

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.

I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

# Best, Francis

From:

(b) (6)

Sent: Friday, February 12, 2021 2:32 PM

To: Collins, Francis (NIH/OD) [E] <

(b) (6)

Subject: Re: [EXTERNAL] a few follow ups

#### Francis

If you prefer a smaller group , I am pleased also to present the protease drug highlights myself and john together w our CEO Albert Bourla from Pfizer to meet the three of you

Best

(b) (6)

Sent from my iPhone

On Feb 12, 2021, at 14:16,

(b)(6)

> wrote:

**Dear Francis** 

l and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team . We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you, Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday) to discuss how we can work together on our IV and ORAL pan-Corona virus protease inhibitor (Pi) drugs.

In this time of SARSCov2 viral evolution, they seems like a drug class w great promise.

We have submitted the IV PI drug to ACTIV w positive reception . We are planning to submit the oral PI drug to ACTIV on Wednesday next week .

Albert will join me in the meeting w you. If you want to have some more detailed background science on the drugs, I was thinking to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte Allerton. Liesa participated in ACTIV since the start within therapeutics related work streams.

Look forward to your response

Best (b) (6)	
(0) (0)	
Sent from my iPhone	

On Feb 11, 2021, at 05:26, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all coronaviruses is extremely encouraging – will this even cure the common cold? (a) I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Wholley into that conversation soon.

Best, Francis

From: (b) (6)

Sent: Wednesday, February 10, 2021 8:36 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: Re: [EXTERNAL] a few follow ups

Hi Francis

Good that you try to correct NYT article but TIME paper was great

The exciting piece with antiviral protease inhibitor (PI) drugs is that they are pancorona virus active wipotential as a drug for any new pandemic coronavirus. They also will inhibit all presently known SARSCov2 mutant variants that mainly affect SPIKE





Mikael

Sent from my iPhone

On Feb 10, 2021, at 06:33, Collins, Francis (NIH/OD) [E]

(b) (6) wrote:

Hi (b) (6)

Just checking in. First, thanks for your kind words that were quoted in the TIME magazine profile – very much appreciated!

Second, I have been distressed by the uninformed characterization of the ACTIV efforts on therapeutics in the New York Times article ten days ago by Carl Zimmer, and a more recent OpEd from Zeke Emanuel et al. The TIME article gave a much more accurate depiction, and I hope that was noticed. My staff and I are working in other ways to correct the record on this – including an upcoming New Yorker article and 60 Minutes segment that will be much more positive!

Third, I am glad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things

about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic – and an advance desperately needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you can tell me about progress there?

All the best, Francis

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] Sent: 7/23/2020 8:28:22 PM To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel Cohen, Myron [ (b)(6)Corey, Larry Victoria Davey [ Desrosiers, Betsy [ Dickens, Jim (b) (6) (b)(6)(NIH/NCATS) [C] | (b) (6) Doroshow, James (NIH/NCI) [E] [ (b) (6) Garner, Carlos Goff, David (NIH/NHLBI) [E] [ Kurilla, Michael (NIH/NCATS) [E] (b)(6)(b) (6) Mensah, George (NIH/NHLBI) [E] [ Nayak, Seema (NIH/NIAID) [E] (b)(6)(b)(6)Payton, Manizhe (NIH/NIAID) [E] [ (b)(6)(b)(6)Resnansky, Laura [resnansky. Sizemore, Christine (NIH/FIC) [E] [ Stein, Peter (b) (6) (b)(6)(FDA/CDER) | Takas, Therese | Vincent, Mike (b)(6)(b)(6)Weinmann, Gail (NIH/NHLBI) [E] [ Srinivasan, Badhri (b)(6)(b)(6)(b)(6)CC: Wachtel, Jonathan | (b)(6)]; Colvis, Christine (NIH/NCATS) [E] [ (b)(6)Eric Hughes Jansen, Kathrin [ Lowy, Douglas (NCI) (b)(6)(b)(6)Read, Sarah (NIH/NIAID) [E] [ Young, John | (b) (6) (b)(6)(b)(6)Criffield, Robin [ Hamilton. Ardiff, Bernadette | (b) (6) (b) (6) Minnich, Beth Melencio, Cheryl (FNIH) [T] [ Nancy (b) (6) (b) (6) (b)(6)Mueller-Reichenstein, Petra [ (b) (6) Pico, Dianna (NIH/NHLBI) [C] [ Quadros, Nora | Katz, Rebecca (NIH/NCATS) [E] (b) (6) (b)(6)]; Hill, Zoe (NIH/NHLBI) [C] Adam, Stacey (FNIH) [T] | (b)(6)(b) (6) (b) (6) ]; Carluccio, Anderson, Margaret | ]; Parker, Ashley (NIH/OD) [E] [ (b) (6) (b) (6) Dana [ Culp, Michelle (NIH/OD) [E] | Gadbois, Ellen (b)(6)(b)(6)(NIH/OD) [E] [ (b) (6) Gonzalez, Nina (b)(6)Heaton, Penny (b)(6)James, Stephanie (FNIH) [T] | (b)(6)Kenny, Dermot Kublin, James | ; Li, Rose | (b)(6)(b)(6)(b)(6)Menetski, Joseph (FNIH) [T] | Qashu, Felicia (NIH/OD) [E] [ : Santos, (b)(6)(b) (6) Michael (FNIH) [T] | Wholley, David (b) (6) Tuvesson, Nancy | (b)(6)(FNIH) [T] [ (b)(6)Bethany Stokes | Collins, Francis (NIH/OD) [E] (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] (b) (6) Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting Attachments: Clinical Trial Capacity Working Group Meeting Agenda 07282020.pdf Location: https://fnih.zoom. (b)(6)Start: 7/28/2020 1:00:00 PM End: 7/28/2020 2:00:00 PM Show Time As: Tentative

Required Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Attendees: Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manzine; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Takas, Therese; Vincent, Mike; Weinmann, Gail Optional Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah Attendees: (NIH/NIAID) [E]; Young, John; Ardiff, Bernadette; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] Zoe (NIH/NHLBI) Hill [C] ( Adam, Stacey (FNIH) [T]; Anderson, Margaret; (b)(6)(b) (6) Carluccio, Dana; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen Ashley (NIH/OD) Parker [E] ( (b)(6)(NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Kenny, Dermot; Kublin, James; Li, Rose; Menetski, Joseph (FNIH) [T]; Qashu, Felicia; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Bethany Stokes; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Dear Colleagues, Attached, please find the agenda for this last meeting of the Clinical Trial Capacity Working Group. With best regards, Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.emai]; Deming, Damon
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Collins, Francis
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              (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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                                                                                  Parker, Ashley (NIH/OD) [E]
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD)
              [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
                                               Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative
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Jonathan
                              ]; Prabhavathi Fernandes [
                                                                                      Rose Li
                (b) (6)
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                            Dana Carluccio |
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(b) (6)	Dave Frankowski [	(b) (6)	Baric, Toni C
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Recurrence: (none)

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From:

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To:

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Dear Preclinical Working Group,

Thank you all for attending our ACTIV preclinical full working group meeting yesterday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments. We have also attached a slide with the subgroup updates we didn't get to during the meeting.

Also attached please find the finalized report for the SARS-CoV-2 summit on antiviral drug development. Sharing with the WG for awareness.

Best Regards, Sarah

Sarah Connelly, PhD Deloitte Consulting, LLP

(b)(6)Tel/Direct: www.deloitte.com ----Original Appointment----From: Menetski, Joseph (FNIH) [T] < (b)(6)Sent: Friday, October 2, 2020 2:19 PM To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b)(6)1; (b)(6)(b) (6) (b)(6): Baric, Ralph; (b) (6) Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b)(6)Adams, Peter Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b)(6)(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette\_baric; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Mason, Stephen; (b)(6)Connelly, Sarah; Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd; (b)(6)Subject: ACTIV Preclinical full working group When: Wednesday, January 20, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada). Where: https://fnih.zoom. (b) (6) Changing time for preclinical WG Joseph Menetski is inviting you to a scheduled Zoom meeting. Join Zoom Meeting https://fnih.zoom.us/ (b)(6)Meeting ID: (b) (6) Passcode: (b) (6) One tap mobile (b) (6) US (Germantown) US (Chicago) Dial by your location (b)(6)US (Germantown) US (Chicago) US (New York) JS (San Jose) US (San Jose) US (Tacoma) US (Houston) Meeting ID: (b) (6) Passcode: (b) (6) Find your local number: https://fnih.zoom.u (b)(6)

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Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 8/18/2020 2:23:39 PM Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William Plump, Andrew | (b) (6) Stoffels, Paul | (b) (6) (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa (b) (6) Anderson, Margaret (b) (6) Chen, Helen Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [ (b) (6) ]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp); Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Tolman, Brett [ (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Castillejos, Carlos Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; FNIH Central Account Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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                        Protasiewicz, Ann [
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                                                                      Riccobene, Kim
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ACTIVEC & Working Group Co-Chair Meeting
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9/9/2020 1:00:00 PM
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Subject:

Location:

Start: End: 9/9/2020 2:00:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]

Optional Attendees: Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, Ellen (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];

Wolinetz, Carrie (NIH/OD) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]

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From: Woodcock, Janet | (b) (6) Sent: 5/13/2020 1:37:51 AM Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf] Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group Flag: Follow up Yes you can share. It's a bit out of date. As I said I'm doing a deeper dive on convalescent plasma and the neutralizing MoAbs. Should have soon. Need to fill in detail of all planned DOD and NIH studies. Should get to that this week. Jw From: Collins, Francis (NIH/OD) [E] < (b)(6)Date: May 12, 2020 at 8:48:22 PM EDT To: Woodcock, Janet < (b)(6)Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group Hi Janet, I just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I share with ACTIV leadership? Francis From: Woodcock, Janet < (b) (6) Sent: Tuesday, May 12, 2020 5:01 PM To: Collins, Francis (NIH/OD) [E] < (b)(6)Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group From: Collins, Francis (NIH/OD) [E] (b)(6)Sent: Tuesday, May 12, 2020 1:31 PM To: Woodcock, Janet < (b)(6)Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group if you can. Otherwise after 7 pm is good From: Woodcock, Janet < (b) (6)

Sent: Tuesday, May 12, 2020 1:08 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

No have to brief higher ups. Later better. Jwv

From: Collins, Francis (NIH/OD) [E] (b) (6)

Date: May 12, 2020 at 12:49:32 PM EDT

To: Woodcock, Janet < (b) (6)

Subject: RE: Letter to the ACTIV Executive Committee

Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes, I would like that. Can you do 3:30?

From: Woodcock, Janet < (b) (6)

Sent: Tuesday, May 12, 2020 11:28 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

From: Wholley, David (FNIH) [T] < (b) (6)

Sent: Tuesday, May 12, 2020 10:46 AM

To: Collins, Francis S (NIH) (b) (6) ; Stoffels, Paul [JJCUS] (b) (6) >; Fauci, Anthony S (NIH) (b) (6) ; Gibbons, Gary H (NIH) (b) (6) Woodcock, Janet >; Dolsten, Mikael

Desrosiers, Betsy Cc: Colvis, Christine M (NIH) < (b) (6) (b)(6)Hughes, (b)(6)Eric < Read, Sarah W (NIH) Jansen, Kathrin (b) (6) Kurilla, Michael G (NIH) ·; Lowy, Douglas R (NIH) (b)(6)(b)(6)Young, John >; Freire, Maria C (NIH) (b)(6)>; Tabak, Lawrence A (NIH) >; Lane, Henry C (NIH) < ; Parker, Ashley S (NIH) (b)(6)(b)(6)(b)(6)Anderson, James M (NIH) (b)(6)>; Austin, Christopher P (NIH) Wolinetz, Carrie D (NIH) (b) (6) (b) (6)

Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

# Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group cochairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

From: Adam, Stacey (FNIH) [T] (b) (6)

Sent: Tuesday, May 12, 2020 9:52 AM

To: Wholley, David (FNIH) [T] (b) (6)

Cc: Read, Sarah (NIH/NIAID) [E] (b) (6) >; Eric Hughes < (b) (6) Carlos O Garner (b) (6) >; Judy Currier < (b) (6) Keith Gottesdiener

(b) (6) ; Amanda Peppercorn < (b) (6) >; Stein, Peter (FDA/CDER)
 (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) (b) (6)</li>

Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Melsheimer, Rich [CNTNL] [ (b) (6) Sent: 10/16/2020 9:12:01 PM Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc] CC: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bfdfccfda71ced-jatkinso]; Chang, Soju (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99b3263e72a94bfa9ded3f82c4dae59c-changsoju]; Gavin, Brian Sadeh, Jonathan [ Beumont-Mauviel, Maria (b) (6) (b) (6) [JRDUS] [ Bharucha David | (b) (6) (b) (6) Ferguson William (b)(6)Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; LaVange, Lisa M Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Gardner, Bobbi (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dd21d20185e4e46a20a6eb89c314580-gardnerbw]; Sandeep Menon Yong, Florence H Trank, Christina (b)(6)(b) (6) Collins, Francis (NIH/OD) [E] (b) (6) Moyo, Vusi [ (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Kimmel, Bridget [JRDUS] Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Marti, Emily (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=970fb6ea63944699aa433fb034a0f63f-carlsone]; Eisnor, Derek (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae393740634d4ec9954494c0c2ef669a-Derek.Eisno]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; Montgomery, O'Sullivan\_Alexandra | Stock, Stephanie [ (b) (6) (b) (6) Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Neta Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d10b8fd5dff411eb1d6f8f4892e27e3-nnelson.tec]; Butler, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4782eaa72024479197826e3d71d5584c-sbutler.tec]; Daniel Benjamin Jr, M.D., Ph.D. [ Theresa Jasion | Molina, Daniel (b) (6) (b)(6)Lind, Brian (NIH/NCATS) [E] (b)(6)Rose Beci | (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486ebcc6ebe34d08a691e66632ed5005-lindbil: O'rourke, Anna (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a43de8d7c474c538615405753ccfb6c-Anna.O rour]; Lori Hudson, Ph.D. Huyen Cao < (b) (6) (b) (6) (b) (6) Huyen Cao (b)(6)Brody, Betty (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecad8c87c49d4f018bd2530beaf4a30d-Betty.Brody]; Chiang, Anna (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa42127fa32b4d0fa0ccce5799cf419f-Anna.Chiang]; Schmidt, Jeffrey (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3431da5ab88f4204858d4c6fe19aaa7a-Jeffrey.Sch]

Subject:

Re: 1st ACTIV-1 patient has been randomized

COLL0000013981-2517534

1999 to go!!

It's been a big day for ACTIV-1!!

Thanks to everyone!

Rich

Sent from my iPhone

On 16 Oct 2020, at 22:49, Austin, Christopher (NIH/NCATS) [E] < (b) (6) wrote:

Woohoo that was fast! Thank you Bill and Jane and team! All best, Chris

	Bozzette, Sam (NI		(b) (6	)			
	Friday, October 16	0					
To: Bo	ucher, Cynthia (NI	H/NCATS) [E] <	(b)	(6)	Atkins	on, Jane (NIH	/NCATS) [E]
<	(b) (6)	Chang, Soju (NI	H/NCATS) [E	] <	(b) (6)	'	(b) (6)
<	(b) (6)	'Gavin, Brian'	(b)	(6)	'Sadeh,	Jonathan'	
<	(b) (6)	'Melsheim	er, Rich [CN	TNL]' <	(b) (6	) 'Be	eumont-Mauviel,
Maria	[JRDUS]' <	(b) (6)	'Bharucha_			(b) (6)	
'Fergu	son_William' <	(b) (6)		Eric Hu	ughes <	(b) (6)	Read
Sarah	(NIH/NIAID) [E] <	(b) (6)	'LaVaı				Proschan,
Micha	el (NIH/NIAID) [E]	(b) (6)	)	Gardner,	Bobbi (NIH/	NCATS) [E]	
<	(b) (6)	'Sandeep Mer	non' <	(b	) (6)	'Yong	, Florence H'
<	(b) (6)	'Trank	, Christina'	<	(b) (6)	'Moy	o, Vusi'
<	(b) (6)	Collins, Franc	is (NIH/OD)	[E] <	(b) (6)	'Kimme	l, Bridget [JRDUS
<	(b) (6)	Adam, Stacey (	FNIH) [T] <	(b) (d	6) Ma	arti, Emily (NI	H/NCATS) [E]
<	(b) (6)	Eisnor, Derek (	OS/ASPR/BA	ARDA) <	(b) (e	6)	
1	(b) (6)	<	(b) (6)	Aus	stin, Christo	pher (NIH/NO	CATS) [E]
<	(b) (6)	Collins, Francis (	NIH/OD) [E]	<	(b) (6)	Woodcoc	k, Janet
(FDA/	CDER) <	(b) (6)	Mason	, Robin (C	DS/ASPR/BA	RDA)	
<	(b) (6)						
Cc: 'M	ontgomery, Steph	anie' <	(b) (6)		O'Sul	livan_Alexan	dra
<	(b) (6)	St	ock, Thomas	(HHS/IO	S) <	(b) (6)	Neta Nelson
<	(b) (6)	Butler, Sandy			Daniel	Benjamin Jr, I	M.D., Ph.D.
<	(b) (6)	Theresa Ja	asion <	(b) (		Molina, Da	
<	(b) (6)	Rose Beci <	(b) (6)	L	ind, Brian (I	NIH/NCATS) [	E]
<	(b) (6) N	lason, Robin (OS)	ASPR/BARD	A) <	(b) (6)	O'ro	urke, Anna
(OS/AS	SPR/BARDA) (CTR)			Vicesium annual contact contact	And the control of th	NIH/NCATS) [	[E]
<		Lori Hudson, Ph			"Ho	uyen Cao"	
<		<"Huyen Cao"			Huye	en Cao	
<		Brody, Betty				*	niang, Anna
(OS/AS	SPR/BARDA) <	(b) (6)	Schmidt	, Jeffrey (	OS/ASPR/B	ARDA)	
<	(b) (6)						
Subjec	ct: 1st ACTIV-1 pat	ient has been rar	ndomized				

# Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all! Sam B

# Sam Bozzette. MD, PhD

Chief Medical Officer Immediate Office of the Director National Center for Advancing Translational Sciences National Institutes of Health

6701 Democracy Blvd., Room 926
Bethesda, MD 20892
(Use ZIP code 20817 for overnight mail or courier)
Phone:
(b) (6)

E-mail: 5 (b) (6)

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent:

7/16/2020 4:11:37 PM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC:

Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]

Subject: FW: ACTIV Home Nursing Playbook ready for use!

Since you asked...

From: Tountas, Karen (FNIH) [T] < (b) (6)

**Sent:** Thursday, July 16, 2020 11:05 AM **To:** Wholley, David (FNIH) [T] < (b) (6)

Subject: RE: ACTIV Home Nursing Playbook ready for use!

Just an FYI... I sent this final version to the ACTIV-2 ops team and received this from Judy Currier — "Thanks Karen, This is really helpful and just in time as we work to finalize our plans for home health in ACTIV-2. It will be of great value to the ACTIV-2 team."

Good to know all that work was not in vain! Let's hope the next four are also helpful for ACTIV. @

From: Tountas, Karen (FNIH) [T] Sent: Thursday, July 16, 2020 8:58 AM To: Colvis, Christine (NIH/NCATS) [E] (b) (6) : Hughes, Eric < (b) (6) >; Jansen, Kathrin (b) (6) (b) (6) Read, Sarah (NIH/NIAID) [E] ; Lowy, Douglas (NCI) < (b) (6) Young, John (b) (6) Cc: Adam, Stacey (FNIH) [T] : James, Stephanie (FNIH) [T] < : Menetski, Joseph (b) (6) (b) (6) (FNIH)[T] <Santos, Michael (FNIH) [T] (b) (6) ; Wholley, David (FNIH) [T] (b)(6)Desrosiers, Betsy : Kurilla, Michael (NIH/NCATS) [E] (b)(6)>; Kelly, Eileen Wachtel, Jonathan (b) (6) (b) (6) (b)(6)

Subject: ACTIV Home Nursing Playbook ready for use!

Dear ACTIV Working Group co-chairs,

On behalf of the ACTIV Clinical Trial Capacity Working Group, I am pleased to announce the completion of the ACTIV Home Nursing Playbook (attached). Many thanks to Betsy Desrosiers and Eileen Kelly (cc'd) and their teams at Merck and Novartis, respectively, for sharing their knowledge, lessons learned, and materials to enhance and accelerate ACTIV's clinical trial efforts. And, many thanks to Jonathan and Olivia (Deloitte) for creating an organized and user-friendly structure for these playbooks.

We know that the ACTIV-2 operations team, who has used an earlier draft of this playbook, found the details enclosed very useful and we hope that other COVID-focused clinical trial protocol and operations teams will also. Please feel free to distribute to your teams, and provide any and all feedback (positive and constructive critiques).

Of note, Betsy and Eileen have offered to make themselves and their team members available to walk through the playbook with clinical trials teams as requested.

With best regards, Karen

Karen H. Tountas, PhD

Scientific Program Manager

# Foundation for the National Institutes of Health

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852







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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent: 5/31/2020 12:53:31 AM

To: Dolsten, Mikael |

Sogaard, Morten [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp];

Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Collins, Francis (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(b)(6)

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Marks, Peter (FDA/CBER)

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Cheng, Seng

(b) (6) Protasiewicz, Ann (b) (6)

Subject: RE: [EXTERNAL] RE: Preparation for Monday's AMP Gene Therapy teleconference

Sounds like a good idea. Let me know if you think we all need to talk more on Monday.

From:

CC:

Sent: Saturday, May 30, 2020 6:45 PM

To: Wholley, David (FNIH) [T] < (b) (6)

Cc: Sogaard, Morten < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Hoffmann, Steve (FNIH) [T] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6) Marks, Peter (FDA/CBER)

< (b) (6) Cheng, Seng < (b) (6) Protasiewicz, Ann

(b) (6)

Subject: Re: [EXTERNAL] RE: Preparation for Monday's AMP Gene Therapy teleconference

Let's circulate the GTx proposal before HEVER as I think it was at a HEVER meeting a while ago that I and Francis brought to the table a proposal around GTx rare disease

Peter Marks has also been a driving force

We may at the end of HEVER ask for comments on the white paper GTx and encourage more groups to join.

Sent from my iPhone

On May 30, 2020, at 17:35, Wholley, David (FNIH) [T] < (b) (6) wrote:

#### Hi, Morten,

Sorry for not responding sooner to your meeting notice but have been heads down on COVID (ACTIV) stuff. The final white paper is attached. I must confess I am not entirely sure what the agenda should be the call you arranged for Monday's, but am happy to jump on the phone if there needs to be a follow-up discussion. My official next step is to get the minutes from our EC call Friday (which our writer tells us I should have by Monday morning) and send out a formal ballot to the EC (we were missing Paul Stoffels and John Reed on Friday's call, unfortunately, and did not complete a final vote). If, as I expect, the formal vote is to proceed the typical next step is for FNIH to shop the white paper to companies that may be interested in joining the existing group to turn the white paper level plan into a final research plan with well-defined budgets and specific milestones. FNIH would run that additional planning process (which Joe and Steve would lead). Normally I would think we'd use Hever as a venue to make the additional companies aware of the opportunity (and I imagine we do owe them a report out on the progress of this effort given that it originated there), but I understand the plan for this Tuesday's Hever

call is pretty much focused on the global response to COVID. I defer naturally to Mikael on how he'd like to handle this. Perhaps we can talk about that more on Monday. Regards,

### David

From: Soga	ard, Morten	(b) (6)		
Sent: Satur	day, May 30	, 2020 12:12 PM		
To: Menets	ski, Joseph (F	[N][T] < (b) (6)	) Hoffmann, Ste	eve (FNIH) [T]
< (t	0) (6)	Wholley, David (FNIH)	[T] < (b) (6)	Collins, Francis (NIH/OD) [E
< (b)	(6)	(b) (6)	(b) (6)	Marks, Peter (FDA/CBER)
< <u>Peter.M</u>	(b) (6)			
Cc: Sogaard	d, Morten <	(b) (6)	Cheng, Seng <	(b) (6)
Protasiewio	cz, Ann <	(b) (6)		
Subject: Pr	eparation fo	r Monday's AMP Gene	Therapy teleconference	e

Dear Joe, Steve and David,

Congratulations on the AMP Gene therapy white paper – that is an important milestone and achievement. I wondered if you could share the latest version that was shared at Friday's' AMP meeting so we can share with the full group? Please, also let me/us know of any other pre-read material.

Dear Mikael, Francis and Peter,

I assume that the main focus of Monday's meeting will be to follow up on the AMP discussion and come together around next steps in a bit more detail?

Best wishes, Morten

<AMP Gene Therapy Concept\_5.29.2020.pdf>

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] Sent: 1/12/2021 9:56:20 PM To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Carter, Kara Cavaleri, Marco | (b) (6) Cihlar, Tomas (b)(6)Collins, Francis (NIH/OD) [E] [ (b)(6)Corey, Larry | (b)(6)Culp, Michelle (NIH/OD) [E] [ (b)(6)Victoria Davev I (b) (6) Disbrow, Gary (OS/ASPR/BARDA) [ Dolsten, Mikael | Erbelding, Emily (b) (6) (b) (6) (NIH/NIAID) [E] [ Erck, Stan | (b)(6)Gadbois, Ellen (NIH/OD) [E] (b)(6)Hudson, Thomas (b)(6)Gibbons, Gary (NIH/NHLBI) [E] | (b)(6)James, Stephanie (FNIH) [T] [ : Johnson, Robert (OS/ASPR/BARDA) (b)(6)(b) (6) Lane, Cliff (NIH/NIAID) [E] Kramer, Lynn (b) (6) (b)(6)Marks, Peter (FDA/CBER) I (b)(6)Lepore, John (b) (6) (b) (6) 1; Mascola, John (NIH/VRC) [E] (b)(6)Meeker, David (b) (6) Menetski, Joseph (FNIH) [T] (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b)(6)Pandya, Hitesh Parker, Ashley (NIH/OD) [E] | Perlmutter, Roger (b) (6) (b)(6)Plenge, Robert | Plump, Andy (b) (6) (b) (6) Rachel Ramoni I Reese, David | (b)(6)(b) (6) (b) (6) Rouse. Doris Santos, Michael (FNIH) [T] [ Skovronsky, Daniel (b) (6) (b) (6) (b)(6)Stein, Peter (FDA/CDER) | (b) (6) Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael Tsai, John Vessey, Rupert [ Virgin, (b) (6) (b) (6) (b) (6) Skip I Wholley, David (FNIH) [T] [ Young, John (b) (6) (b)(6)(b)(6)Colvis, Christine (NIH/NCATS) [E] | ]; Desrosiers, Betsy | (b)(6)(b)(6)Eric Hughes I ]; Jansen, Kathrin | (b) (6) ]; Kurilla, Michael (NIH/NCATS) (b)(6)Lowy, Douglas (NCI) [ Read, Sarah (NIH/NIAID) [E] [E] [ (b)(6)(b) (6) Anderson, James (NIH/OD) [E] Burklow, John (NIH/OD) [E] (b) (6) (b)(6)Carluccio, Dana | Castillejos, Carlos (b)(6)(b) (6) FNIH Central Account (b) (6) Hallett, Adrienne (NIH/OD) [E] (b) (6) (b)(6)]; Lumsden, Joanne (NIH/NCATS) [C] (b)(6)Myles, Renate (NIH/OD) [E] | ]; Wolinetz, Carrie (NIH/OD) [E] [ Adam, Stacey (FNIH) [T] (b) (6) (b)(6)Margaret Anderson | Appell, Evan | (b) (6) Chen, (b)(6)(b)(6)Connelly, Sarah | Gonzalez, Nina Helen [ (b)(6)(b)(6)(b) (6) Hawk, Harrison | (b) (6) Mendelson, Jesse (b)(6)Nasr, Hana Sorosa, Alex 1; Stratton, Benjamin (b)(6)(b)(6)(b)(6)btolman [ (b)(6)Wachtel, Jonathan (b)(6)Meltzer, Embry, Alan (NIH/NIAID) [E] [ Abbey (FNIH) [T] Venkayya, Rajeev (b)(6)(b)(6)Rutter, Joni (NIH/NCATS) [E] Cwalina, Alex (b)(6)(b)(6)Kessler, David (HHS/IOS) [ (b) (6) (b) (6) Bancel, Stephane (b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene Pao, William Paul, Steve | (b) (6) (b)(6)(b) (6) Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Reed, John (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc] CC: Austin, Sarah (NIH/NIAID) [E] [aust (b) (6) Barasch, Kimberly (NIH/NIAID) [C] Bell, Julie Burrus-Shaw, Cyndi (NIH/OD) [E] (b)(6)(b) (6) (b) (6) ; Carver, Trea (NIH) [C] [ (b) (6) ]; Caulfied, Anita (b) (6) ; Coan, Conrad, Patricia (NIH/NIAID) [E] | Amanda | ]; Dimishkov, Roxanne (b)(6)(b) (6) (NIH/NHLBI) [C] | Edl, Susan I Fuhrer, Nicole (b)(6)(b) (6) Giorgi, Sara | (b)(6)Hoban, Michelle [ (b) (6) (b) (6) Hoffstetter, Renata (FNIH) [T] [ Iberdemaj, Vaide | Jenkins, (b)(6)(b)(6)Lever, Susan Magbie-Robinson, Kim Christine S. (b) (6) (b) (6) (NIH/OD) [C] [ Martin, Melisa [ McManus, Ayanna (NIH/OD) [E] (b) (6) (b) (6) Minnich, Beth [ Perala, Mie | (b) (6) (b) (6) (b)(6)Protasiewicz, Ann | (b) (6) Riccobene, Kim [ (b) (6) ]; Riggin, Mary

	(b) (6)	Ripley, Nadege [	(b) (6)	Schus	ter, Donna	
1	(b) (6)	Sepulveda, Dorir	a (FNIH) [T]	(b) (6)	Simon, D	ina (NIH/OD) [C]
	(b) (6)	Suhana, Tina (NIH/VRC) [I	E][ (b) (6	) Thom	nas, Ashley (F	DA/CDER)
1	(b) (6)	Wood, Gretchen	(NIH/OD) [E] [	(b) (6)	Togashi,	Mieko (NIH/NCI) [E]
1	(b) (6)	Underwood, Nan	cyl	(b) (6)	Zottoli,	Jessica
1	(b) (6)	Hughes, Karen (NIH	/OD) [E] [	(b) (6)	Regan, Dor	nna M
1	(b) (6)	Plenge, Robert [	(b) (6)	Vessey, I	Rupert [	(b) (6)
Burk	e, Leslie [	(b) (6) Moghir	ninia, Mahtab (Ni	H/NCATS) [E] [	(b	) (6)
Lowy	. Douglas (NIH/N	NCI) [E] [ (b) (6)				

Subject: ACTIV Leadership Team Call #15

Location: https://fnih.zoom.us/ (b) (6)

Start: 4/28/2021 12:30:00 PM End: 4/28/2021 2:00:00 PM

Show Time As: Busy

### Required Attendees:

Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; Rutter, Joni (NIH/NCATS) [E]; Cwalina, Alex; Kessler, David (HHS/IOS)

# Optional Attendees:

Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Regan, Donna M; Plenge, Robert; Vessey, Rupert; Burke, Leslie; Moghiminia, Mahtab (NIH/NCATS) [E]; Lowy, Douglas (NIH/NCI) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]

Sent: 5/29/2020 10:49:02 PM

To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

Subject: Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30



On May 29, 2020, at 6:44 PM, Collins, Francis (NIH/OD) [E] < (b) (6) wrote:

Yes, she is waiting to see the draft ppts and will advise on the strategy then.

Sent from my iPhone

On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] < (b) (6) wrote:

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] < (b) (6) wrote:

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] < (b) (6)

Sent: Friday, May 29, 2020 1:59 PM

To: Collins, Francis (NIH/OD) [E] < (b) (6)

Cc: Adam, Stacey (FNIH) [T] < (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Gonzalez,

Nina < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)

Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a portfolio approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) in progress
  - o ACTIV hiVIG (sponsored by NIAID) in progress
  - ACTIV-1 Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
  - ACTIV-2\*- Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) - (Phase II/III) - projected launch June
  - ACTIV-3\* Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
  - ACTIV-5 De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) similar design to the mAb protocols, networks/sites/agents in discussions now projected launch August (if needed; i.e. if agents are not incorporated into mAb protocols)
    - \* current priority
    - [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
  - Prioritization Process (v 2.0) for ACTIV: (slide 14 from May 20 EC deck)
  - Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
     [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
  - Prioritization and Protocol Design: Who is Involved two-box slide containing names and affiliations of those involved in the Proritization and MP Subgroups (quality folks!)
  - ACTIV-1 Protocol for immunomodulators
    - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
    - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
    - All 3 either have initial Phase II data or are currently running companysponsored Phase II trials = high POS
    - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
    - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
    - Protocol is 80% complete

- Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
  - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
- All three companies have written their sections of the protocols, which are being merged into the master design
- Working with OWS/BARDA on choice of CRO to run the trial; r (b) (5)
- "ACTIV-4" Protocol for anticoagulants
  - Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)
fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>

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From:

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To:

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Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

Thank you for your participation in the last meeting of the Vaccines Working Group. Attached are the notes from that meeting and the slides that Matt Biggerstaff presented.

Please let us know if you have any questions or suggestions. We look forward to engaging with you in this week's meetings.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, May 27, 2020 1:12 PM

Subject: Agenda for ACTIV Vaccines Working Group meeting: Tomorrow, 28 May

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

The agenda for Vaccines Working Group meeting tomorrow (Thursday) at 2pm ET (11am PT / 8pm CEST) is:

- Matt Biggerstaff, from CDC's modeling team, will present on predictive modeling of incidence to inform vaccine efficacy trials
- · Time permitting, we will discuss updates from the Sub-Groups

Given the importance of the first agenda item to the Vaccines Clinical Trials Sub-Group, we are inviting that group to join the meeting. The calendar invite follows this note. As a reminder, we have two meetings scheduled tomorrow, and many of you will also receive an email about the Vaccines Clinical Trials Sub-Group meeting (at 11am ET).

We also want to provide a preview of a coming set of requests: As we have previously discussed, NIAID is constituting a DSMB for the efficacy trials that are implemented with US government funding. The Vaccines Clinical Trials Sub-Group was asked for DSMB member recommendations: thanks to those who sent input. We will be sharing a list of potential DSMB members from NIAID with the Vaccines Clinical Trials Sub-Group (cc'ing the Working Group) today for feedback. Based on that feedback, NIAID will propose a list of members and alternates. We will circulate that list to the Vaccines Working Group (cc'ing the Sub-Group) for final input before NIAID finalizes the list and reaches out to proposed members. We apologize in advance for the short turn-around times that will be requested given the necessity of finalizing the DSMB members in time for an early July trial start.

We're looking forward to the meeting tomorrow. Please feel free to reach out with any questions or suggestions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

(b) (6) fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From:		[T] [/O=EXCHANGELABS/OU CN=RECIPIENTS/CN=DCD87			ISJ4]
Sent:	4/17/2020 8:04:45 PI	M			
Sent: To:	Bozzette, Sam (NIH/N (FYDIBOHF23SPDLT)/ [/o=ExchangeLabs/ou (FYDIBOHF23SPDLT)/ (FDA/CDER) [/o=Exch (FYDIBOHF23SPDLT)/ [/o=ExchangeLabs/ou (FYDIBOHF23SPDLT)/ (FDA/CDER) [/o=Exch (FYDIBOHF23SPDLT)/ [	ICATS) [E] [/o=ExchangeLab: cn=Recipients/cn=85f05a36 i=Exchange Administrative ( cn=Recipients/cn=219ecac4 angeLabs/ou=Exchange Adr cn=Recipients/cn=f6b8f588 i=Exchange Administrative ( cn=Recipients/cn=890082c7 angeLabs/ou=Exchange Adr cn=Recipients/cn=c495c3ee Keith Gottesdiener [ LaVange, Lisa M [ (b) (6) AmanaxchangeLabs/ou=Exchange	19cf47c7ae39d7bcf Group  1faae4ebab8a45ce86 ministrative Group 067140fe988f0832c Group 7c1e34902b0f53532 ministrative Group 125ca461ba6a829b1 (b) (6) (b) (6) da Peppercorn   Administrative Group	Oaac88d-bozzettesaa ee2490c3-joan_butte 2387725-Sylva.Colli] Ocd16650-jscurrier.n 24062448-DECLARO Eric Hugh Elliott Levy   (b) (6)	er]; Collins, Sylva ; Judy Currier n]; De Claro, R. Angelo R.fd]; Mark Eisner es (b) (6) Sandeep Proschan, Michael
	[E] [/o=ExchangeLabs (FYDIBOHF23SPDLT)/   (b) (6) (FYDIBOHF23SPDLT)/ (FDA/CDER) [/o=Exch (FYDIBOHF23SPDLT)/ [/o=ExchangeLabs/ou (FYDIBOHF23SPDLT)/   (b) (6) (FYDIBOHF23SPDLT)/ [/o=ExchangeLabs/ou (FYDIBOHF23SPDLT)/ [/o=ExchangeLabs/ou (FYDIBOHF23SPDLT)/   (b) (6) [/o=ExchangeLabs/o	cn=Recipients/cn=a583ecec angeLabs/ou=Exchange Adr cn=Recipients/cn=35c28910 angeLabs/ou=Exchange Adr cn=Recipients/cn=ae30a026 u=Exchange Administrative 0 cn=Recipients/cn=40b4c445	ve Group D38004a199ae6e0b (FDA/CDER) [/o=Ex 1842c44b18bb6fcd3 ministrative Group D59134111a3ed28f9 ministrative Group e983e4e8a979dfec7 Group G6b14464788f31fe7 /NCATS) [C] [/o=Exc D404e46caba73079c Group B481b4b39ba7e62a   (b) ( Group	ac2226099-readsa]; /changeLabs/ou=ExchangeLabs/ou=ExchangeLabs/ou=Exchange29042aad-RUBIND.fc/257a1802-shenyu.fd/bcaa09bc-FARLEYJ.fc/hangeLabs/ou=ExchangeLabs/	Amanda Peppercorn lange Administrative Group ]; Rubin, Daniel B.  da]; Shen, Yuan Li  a]; Farley, John (FDA/CDER)  la]; Bascles, Lionel lage Administrative Group Stein, Peter (FDA/CDER)
CC:	Mary Biggs   Tountas, Karen (FNIH (FYDIBOHF23SPDLT)/   (b) (6) [/o=ExchangeLabs/ou (FYDIBOHF23SPDLT)/   (b) (6)   (b) (6) (FYDIBOHF23SPDLT)/ [T] [/o=ExchangeLabs (FYDIBOHF23SPDLT)/   (b) (6)	(b) (6) Demarcus [ ) [T] [/o=ExchangeLabs/ou= cn=Recipients/cn=40c04feff Elizabeth Kim [ u=Exchange Administrative ( cn=Recipients/cn=306b224 Lucas Smalldon [ Wholley, David (FNI cn=Recipients/cn=cd9e702f c/ou=Exchange Administraticn=Recipients/cn=279e14fa (b) Wung, Pet	(b) (6) Exchange Administr 6f1e46f5b750753cd (b) (6) Parke Group 4466140faa95aaaaf (b) (6) (H) [T] [/o=Exchange cf28414883d0b699 we Group 7428415bb86087d6	Macone, Erinative Group 5a14f93-tountaskh]; er, Ashley (NIH/OD) [i e06ebd70-parkeras]; 6) Bu Labs/ou=Exchange A 6d677257-wholleyd]	Wachtel, Jonathan  [All Properties of the Control o
Subject:	(b) ( RE: ACTIV TX-Clinical	(6) WG Master Protocol Subgro	oup - 2nd Meeting (I	Materials Attached)	
40000000000000000000000000000000000000					

Hi Sam,

I believe we will be trying to take into account smaller Phase II trials, as well. More on that next week, we have been reviewing some additional protocols. Appreciate you raising it for clarification.

Thanks,

### Stacev

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct:

(b) (6) Mobile: (b) (6)

From: B	ozzette, Sam	(NIH/NCAT	rs) [F] <	(b) (6)					
	ursday, April	ALL THE PARTY OF T		(0) (0)					
	m, Stacey (FN	27		Butterto	n, Joan <		(b) (6)	C	Collins, Sylva
									Angelo (FDA/CDEF
<	(b) (6)		Mark Eisner <						
<	(b) (6)		Eric Hughes	<	(b) (6)		LaVange, Lis	sa M <	(b) (6)
Elliott Le	evy < (	b) (6)	Sandeep N	1enon <	(b	) (6)	A	Amanda F	Peppercorn
<	(b) (6)		Proschan,			] <	(b) (6)		Read, Sarah
NIH/NI	AID) [E] <	(b) (6)	Ama	nda Pepper	corn <		(b) (6)		Price, Dionne
FDA/CD	DER) <	(b) (6)	Rub	oin, Daniel I	B. (FDA/CDEF	R) <	(b) (6)	)	Shen, Yuan Li
FDA/CD	)ER) <	(b) (6)	Far	ley, John (F	DA/CDER) <		(b) (6)	Ba	scles, Lionel
<	(b) (6)		Dickens, Jim (I	NIH/NCATS	) [C] <	(b) (6	)	Stein, Pe	ter (FDA/CDER)
<	(b) (6)	Vin	cent, Michael	<	(b) (6)		Desrosiers	, Betsy	
<	(b) (6)	)	Goff, Da	vid (NIH/NI	HLBI) [E] <	(b) (	(6)		
Cc: Mar	y Biggs <	(b) (6)	Dem	arcus <	(b) (6	)	Macon	e, Erin <	(b) (6)
Tountas	, Karen (FNIH	) [T] <	(b) (6)	Wachtel,	Jonathan <		(b) (6)	Eliz	abeth Kim
<	(b) (6)	Parker,	Ashley (NIH/O	D) [E] <	(b) (6)		Rose Li Ce	ntral Acc	ount
<	(b) (6)		Lucas Smalldor	1 <	(b) (	6)		Butcher,	Tina
<	(b) (6)	W	/holley, David (	(FNIH) [T] <	(b) (6	)	Melencio,	Cheryl (F	NIH) [T]
<	(b) (6)	Kelly Be	eazley <	(b)	(6)	٧	Vung, Peter	/US	
<peter.< td=""><td>(b) (6)</td><td>Gre</td><td>eg Richards &lt;</td><td></td><td>(b) (6)</td><td></td><td></td><td></td><td></td></peter.<>	(b) (6)	Gre	eg Richards <		(b) (6)				
Subject:	RE: ACTIV TX	-Clinical W	/G Master Prot	ocol Subgro	oup - 2nd Me	eeting (N	Naterials At	tached)	

### Hello:

Wondering where in development that agents would be candidates for inclusion into the platform trial(s) need to be? The tone of the discussion seems to be indicate that we are intending these protocols to support relatively large phase 3 evaluations. What about products that need phase 2 (particularly from small companies)? Would we try to roll them in (seems hard), generate another set of master protocols, leave them to flourish (or not) on their own, or something else?

S

----Original Appointment----

From: Adam, Stacey (FNIH) [T] < (b) (6)

Sent: Wednesday, April 15, 2020 6:10 PM

To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; LaVange, Lisa M; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Bascles, Lionel; Dickens, Jim (NIH/NCATS) [C]; Stein, Peter (FDA/CDER); Vincent, Michael; Desrosiers, Betsy; Goff, David (NIH/NHLBI) [E]

Cc: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Kelly Beazley; Wung, Peter /US; Greg Richards

Subject: ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting (Materials Attached) When: Thursday, April 16, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: https://zoom.us/ (b)(6)

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you all for being so quick to reply and making yourselves available for a second meeting on such short notice!

As discussed yesterday, we have tried to synthesize the main points from our discuss and put together just a few slides to pressure test what we thought we heard.

As we think we defined the patient populations and the order of priority with which we should address them during our last meeting. We hope to come out of today's meeting with a decision on whether to engage/sign on to existing master protocols and enhance them (new agents, more resources, more sites, etc.) or to create a who new protocol.

#### Please see attached:

- 1. Agenda
- 2. Slides for today's meeting
- 3. Copies of the protocols for today's discuss that we could access
  - a. ACTG
  - b. ACTT v2
  - c. REMAP-CAP + Pandemic Amendment
    - i. https://www.remapcap.org/coronavirus provides a summary of changes to the REMAP-CAP protocol in order to update to the COVID population

NOTE: We are still working on access to ORCHID.

Kind regards,

Stacey, on behalf of the ACTIV TX-Clinical WG

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                      US (Houston)
Meeting ID:
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Password: (b) (6)
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(b) (6)

From:

Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent:

8/26/2020 11:43:09 AM

To:

Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]

Subject:

RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Ok, thank you.

From: Allen-Gifford, Patrice (NIH/OD) [E] <

(b)(6)

Sent: Wednesday, August 26, 2020 7:34 AM
To: Parker, Ashley (NIH/OD) [E] < (b)

(b) (6)

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Yes, thanks, I was on but I'm not sure all of them were. Also, I am including the entire zoom link info (include call in #s although I think just the zoom info should be sufficient.

From: Parker, Ashley (NIH/OD) [E] <

(b)(6)

Sent: Wednesday, August 26, 2020 7:32 AM

To: Allen-Gifford, Patrice (NIH/OD) [E] <

(b) (6)

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

That's a great idea - it was the COVID-19 ICD Update conference call.

Thanks, Ashley

From: Allen-Gifford, Patrice (NIH/OD) [E] <

(b) (6)

Sent: Wednesday, August 26, 2020 7:28 AM

To: Parker, Ashley (NIH/OD) [E] <

(b) (6)

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thanks Ashley. I have it ready to go and had made the same adjustments. One question: rather than conference call, should it reference the COVID-19 call so ICDs who didn't participate in that won't think they missed an ICD meeting?

From: Parker, Ashley (NIH/OD) [E]

(b) (6)

Sent: Wednesday, August 26, 2020 7:25 AM

To: Collins, Francis (NIH/OD) [E]

(b) (6)

; Allen-Gifford, Patrice (NIH/OD) [E]

(b) (6)

Cc: Wholley, David (FNIH) [T] <

(b) (6)

Melencio, Cheryl (FNIH) [T]

(b) (6)

; Gladman, Jordan

(NIH/OD) [E] <

(b) (6)

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thank you, Francis.

Good morning Patrice,

I've made a few adjustments to the email below to go out to the ICD ONLY list this morning and reattached the materials.

Thanks, Ashley

To: ICD-ONLY-L@LIST.NIH.GOV

Cc: Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6)

Bcc: Parker, Ashley (NIH/OD) [E] (b) (6)

Dear Colleagues,

As discussed during our conference call yesterday, ICDs (principals only please; no surrogates or additional staff) are invited to join the virtual ACTIV leadership team meeting today August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you, Francis

From: Collins, Francis (NIH/OD) [E] < (b) (6)

**Sent:** Wednesday, August 26, 2020 5:57 AM **To:** Parker, Ashley (NIH/OD) [E] < (b) (6)

Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) ; Gladman, Jordan

(NIH/OD) [E] (b) (6) ; Allen-Gifford, Patrice (NIH/OD) [E] (

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Be sure to change the text of the e-mail from "tomorrow" to "today".

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, August 26, 2020 5:56 AM

**To**: Parker, Ashley (NIH/OD) [E] < (b) (6)

Cc: Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6) ; Gladman, Jordan

(NIH/OD) [E] (b) (6) Allen-Gifford, Patrice (NIH/OD) [E] < (b) (6)

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Yes, this note would be great. Looping in Exec Sec to ask that it be sent first thing this morning.

Francis

From: Parker, Ashley (NIH/OD) [E] < (b) (6)

Sent: Tuesday, August 25, 2020 10:52 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

 $\textbf{Cc: Wholley, David (FNIH) [T]} \qquad \qquad \textbf{(b) (6)} \qquad \qquad \textbf{>; Melencio, Cheryl (FNIH) [T]} \qquad \qquad \textbf{(b) (6)} \qquad \qquad \textbf{; Gladman, Jordan}$ 

(NIH/OD) [E] (b) (6)

Subject: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

Hi Francis,

To ensure the ICDs receive the information for the ACTIV LT meeting tomorrow – would you like to forward the following to the ICD only list. Below is a draft note for consideration.

To: ICD-ONLY-L@LIST.NIH.GOV

Cc: Wholley, David (FNIH) [T] <	(b) (6)	Melencio, Cheryl (FNIH) [T] <	(b) (6)	
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Dear Colleagues,

As discussed during our conference call this afternoon, ICDs (principals only please; no surrogates or additional staff) are invited to join the virtual ACTIV leadership team meeting tomorrow August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you, Francis

		eryl (FNIH) [T] <		On Be	half Of Who	lley, David (	FNIH) [T]		
	(202)	st 25, 2020 9:47 PN		L) (C)	Danaal Sta				
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		/holley, David (FNIH						, , , , ,	, 0,
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	(0) (0)	(Desrosiers,	Betsv	(b)	(6)	Eric	Hughes	o	
<	(b) (6)	Jansen, K	athrin	(b) (6	)	Kurilla, Mid	hael (NIH/NC	ATS) [E]	
	(5) (5)	(Lowy, Doug	las (NCI)	(b) (6)	>; Read, Sar	ah (NIH/NIA	(ID) [E]	(b) (6)	:
Young	. John	(b) (6)	<b>1</b>	( ) ( )		A Section of the sect		.,,,	
Cc: Ad	am, Stacev (FN	VIH) [T] < (b) (6	5) Alv	arez, Rosa <	(b)	(6)	Anderson,	Margaret	
	(b) (6)	NIH) [T] < (b) (6 ; Chen,	Helen <	(b) (6)	Els	aid, Olivia	(b) (6)	;	
Gonza	lez, Nina	(b) (6)	>; Hawk	, Harrison	(b) (6)	; ;	Лenetski, Jose	ph (FNIH) [T]	
	(b) (6)	: Santos, Michael	(FNIH) [T] <	(b) (d	Stra	tton, Benjai	min <	(b) (6)	
btolma				(FNIH) [T] <			chtel, Jonatha		
	(b) (6)	Wholley, Day		raci confirmantedire			ames (NIH/OD		
	(b) (6)		A 10 TO	NIH/NCATS)	the second secon	(b) (6)	- 12	John (NIH/OD	) [E]
<	(b) (6)	: Castillejos, Car		(b) (6)		chelle (NIH/			KT/4 LT4006™3
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	(b) (6)	Gadbois, Ellen (NIF	I/OD/ [E]	(b) (d		Jallatt Adrie	enne (NIH/OD	1 [ ]	

	(b) (6)	Lane, Cliff (NIH/NIAID) [E] <	(b) (6)	) Myles,	, Renate (NIH/OD) [E]
	(b) (6)	; Parker, Ashley (NIH/OD) [E]	(b) (6)	; Tabak,	Lawrence (NIH/OD) [E]
	(b) (6)	; Wolinetz, Carrie (NIH/OD) [E]	< (	(b) (6)	Burklow, John (NIH/OD) [E]
<	(b) (6)	; Gorman, Greta (FNIH) [T]	(b) (6)	>; Hallett, Adrie	enne (NIH/OD) [E]
	(b) (6)	; Meltzer, Abbey (FNIH) [T]	(b) (6)	>; Myles, R	Renate (NIH/OD) [E]
<	(b) (6)	Wolinetz, Carrie (NIH/OD) [E] <	(b) (c	6) Luc	as Smalldon
	(b) (6)	) Villafana, Tonya	<	(b) (6)	;>; Brian Rosen
	(b) (6)				

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

# Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Find your local number: https://fnih.zoom.us/u (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]

Sent:

4/30/2020 4:54:14 PM

To:

Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

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[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Subject: Re: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

# Certainly agree.

From: "Lane, Cliff (NIH/NIAID) [E]" < (b) (6)

Date: Thursday, April 30, 2020 at 12:50 PM

Date: Indisday, April 30, 2020 at 12.30 Th

To: "Wholley, David (FNIH) [T]" < (b) (6) Francis Collins < (b) (6)

Cc: "Tabak, Lawrence (NIH/OD) [E]" < (b) (6) "Freire, Maria (FNIH) [T]" < (b) (6)

Subject: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I received an email yesterday (prior to the press release) from a relatively senior scientist that Gilead has re-considered and would like to be part of ACTIV. I was going to mention it on the call this afternoon. I think having them as part of ACTIV – given they have a strong track-record and likely the first directly acting anti-viral - would be good.

#### Cliff

From: "Wholley, David (FNIH) [T]" < (b) (6)

Date: Thursday, April 30, 2020 at 10:18 AM

**To:** "Collins, Francis (NIH/OD) [E]" < (b) (6) "Lane, Cliff **Subject:** FW: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

"Lane, Cliff (NIH/NIAID) [E]" < (b) (6)

FYI, something to think about.

From:	Bozzette, Sam (	NIH/NCATS) [	[E] < (	b) (6)				
Sent:	Thursday, April 3	30, 2020 9:19	AM					
To: Ad	lam, Stacey (FNI	H) [T] <	(b) (6)	Butterton, J	oan <	(b) (6)	)	Collins, Sylva
(FDA/	CDER) <	(b) (6)	Judy Co	urrier <	(b) (6	5)	De Claro, I	R. Angelo (FDA/CDER)
<	(b) (6)	Ma	rk Eisner <	(b) (6	5)	Keith Gotte	esdiener	
<	(b) (6)	E	Eric Hughes <	(1	b) (6)	LaVan	ge, Lisa M <	(b) (6)
Elliott	Levy < (1	b) (6)	Sandeep Mer	on <	(b) (6	5)	Amanda	Peppercorn
<	(b) (6)		Proschan, Mi	chael (NIH/	NIAID) [E] <	(1	b) (6)	Read, Sarah
(NIH/N	NIAID) [E] <	(b) (6)	Amanda	a Peppercor	n <	(b) (6)	)	Price, Dionne
(FDA/	CDER) <	(b) (6)	Rubin,	Daniel B. (I	DA/CDER) <		(b) (6)	Shen, Yuan Li
(FDA/	CDER) <	(b) (6)	Farley	John (FDA,	CDER) <	(b) (	6)	Goff, David (NIH/NHLB)
[E] <	(b) (6)	Vincent,	Michael <	(b)	(6)			
Cc: Ma	ary Biggs <	(b) (6)	Demar	cus <	(b) (6)	N	Aacone, Erin	(b) (6)
Tount	as, Karen (FNIH)	[T] <	b) (6)	Wachtel, Joi	nathan <	(b) (6	6) E	lizabeth Kim
<	(b) (6)	Parker, Ash	ley (NIH/OD)	[E] <	(b) (6)	Butc	her, Tina	
<	(b) (6)	Whol	ley, David (FN	IH) [T] <	(b) (6)	Mele	encio, Cheryl	(FNIH) [T]
<	(b) (6)	Wung, Pete	er/US<	(b) (6)	Qa	ashu, Felicia	a (NIH/OD) [E	Ì

< (b) (6) Stratton, Benjamin < (b) (6)
Subject: Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

Fron	n: "Adam, Stacey	(FNIH) [T]" <	(b) (	(6)							
Date	: Thursday, April	23, 2020 at 8	3:31:00 PM	M							
To: '	'Bozzette, Sam (N	H/NCATS) [E	≣]"	(b) (6)		, "Butt	erton,	Joan"	(b) (	(6)	
"Col	lins, Sylva (FDA/CI	DER)"	(b) (6			udy Curri	er"	(b) (6)		>, "De Cla	ro, R.
Ange	elo (FDA/CDER)"	(	b) (6)		"Mark	Eisner"		(b) (6)	, "Ke	eith Gottesdi	ener"
		(b)	"Eric Hug	hes"		(b) (6)		, "LaVange,	Lisa M"		
<	(b) (6)	"Elliott L	evy"	(b) (6)				enon"	(b	) (6)	
"Am	anda Peppercorn'							ael (NIH/NIAII	Control Control Control		
	(b) (6)	, "Read	I, Sarah (N	NIH/NIAID	) [E]"	(1	b) (6)	, "Ama	anda Pep	percorn"	
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(FDA	\/CDER)" <	(b) (6)						(b) (6)		>, "Farley, Jo	ohn
(FDA	A/CDER)" (b)					NHLBI) [E				ncent, Micha	el"
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Cc: "	'Mary Biggs" <	(b) (6)	i i	"Demarci	us" <	(	(b) (6)	, "M	acone, Er	rin"	
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<	(b) (6)		nu, Felicia					."Stra	tton, Ben	jamin"	
	(b) (6)	>									
		Market St. Commercial		THE SOUTH THE							

Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

- Agenda
- 2. Slides for discussion updated with the decisions from today
- 3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks, Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) | Mobile: (b) (6)

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Wan, Kanny (NIH/NCATS) [C] (b)(6)(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b478497d58dc46e4b3cfdea14f17ecd1-wankk]; RZa (b) (6) Desrosiers, Betsy | Bloom PhD, Jesse D Christopher (b) (6) (b) (6) Murray (b) (6) Subject: **ACTIV Vaccines Working Group meeting** Attachments: Agendas and notes for ACTIV Vaccines Working Group meetings Location: https://nih.zoomgov.com/j/1614753565?pwd=YnBaUFIMdml6ZDZsR1NSM01EbkRrdz09 Start: 2/18/2021 7:00:00 PM End: 2/18/2021 8:00:00 PM Show Time As: Busy Required (b)(6)Lowy, Douglas (NIH/NCI) [E]; (b)(6)Arvin, Ann; Beth Bell Attendees: (b)(6)(b) (6) Cavaleri Marco: (b)(6)Greg Glenn; (b)(6)Haynes, (b) (6) (b)(6)Barton: (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E]; (b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul; (b) (6) : Seals, Jonathan (OS/ASPR/BARDA); (b)(6)(b)(6)Tal Zaks Optional Tolman, Brett; Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (b)(6)Attendees: (NIH/NCI) [E]; Jeneffer Haynes; (b) (6) (b)(6)(b)(6)Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker, Ashley (NIH/OD) [E]; Embry, Alan (NIH/NIAID) [E]; Erbelding, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman; Gonzalez Lopez, Antonio; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD); Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Sotir, Mark (CDC/DDID/NCIRD/DVD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; Bethany Stokes; Kathleen Callahan; Molloy, (b) (6) (b) (6) Delia (DPH); Wood, Gretchen (NIH/OD) [E]; Filip Dubovsky; Jacqueline Miller; Antonio Lanzavecchia; Ann Arvin; Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffield, Robin R.; Marovich, Mary (NIH/NIAID) [E]; FNIH; Barton Haynes, M.D.; Nelson Michael; Gilbert PhD, Peter B; Bloom PhD, Jesse D; (b) (6) Christopher Murray; pennym; Alex Sigal; Ho, David D.; Offit, Paul; Randy Hyer; Adam Bloomfield; Gale Smith; Florence, Clint (NIH/NIAID) [E]; Wan, Kanny (NIH/NCATS) [C]; (b)(6)(b)(6)(b) (6) (b)(6)https://nih.zoomgov. Meeting ID: (b) (6) Passcode: (b) (6) One tap mobile (b) (6) US (San Jose) US (New York) Dial by your location (b)(6)US (San Jose) US (New York) US (San Jose) US Meeting ID: (b) (6)

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Eakin, Ann (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DAFBA298C194F9D9BC13C54FE0CF29A-EAKINAE] Sent: 7/2/2020 1:02:54 AM Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli ]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel | Colvis, Christine (b)(6)(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [ Keith Gottesdiener [ Elliott Levy (b) (6) (b) (6) Koroshetz, Walter (NIH/NINDS) [E] Wung, Peter /US | (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; (b) (6) Rose Li l (b) (6) Mark Krystal [ (b) (6) Prabhavathi Fernandes [ Diamond, Michael [ Sanderson, (b) (6) (b) (6) Philip (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee2d44e63f2645708a3beb2ea1b280a1-sandersonpe]; Tressler, Randall (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tresslerrl]; Dana Carluccio I Menetski, Joseph (FNIH) [T] (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sumit Chanda Rich Colonno (b) (6) (b) (6) Fisher, Robert (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=706cb01f58ef4042aeecc4de5ab72ec1-Robert.Fish] CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-gingchen.de]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Salathin, Carla | (b)(6)(b)(6)(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras] Subject: Re: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting I can make 3:30 but not 3. From: Adam, Stacey (FNIH) [T] < (b) (6) Sent: Wednesday, July 1, 2020 8:59:48 PM To: Eric Hughes < Read, Sarah (NIH/NIAID) [E] < Ruxandra Draghia-(b)(6)(b) (6)

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Dear ACTIV TX-Clinical Agent Prioritization Subgroup and Antiviral Subteam,

While I could not get quorum for the 12-1pm slot for our discussion tomorrow, many of you said you could be available after 3pm. Therefore, could you all let me know if 3-4pm ET tomorrow would work for you to meet?

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Adam, Stacey (FNIH) [T] Sent: Tuesday, June 30, 2020 10:55 PM To: Eric Hughes < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Ruxandra Draghia-Akli < John Mellors < Naimish Patel < (b)(6)Colvis, (b) (6) (b) (6) Christine (NIH/NCATS) [E] < (b) (6) Young, John < (b)(6)Stein, Peter (FDA/CDER) < Poole, Mike < Buchman, Tim (b)(6)(b)(6)(OS/ASPR/BARDA) (CTR) < (b)(6)Vincent, Michael < (b) (6) Keith Gottesdiener < (b)(6)Elliott Levy < Wung, Peter /US (b)(6)Koroshetz, Walter (NIH/NINDS) [E] < Higgs, Elizabeth (b)(6)(b) (6) (NIH/NIAID) [E] < Carlos O Garner < (b)(6)Goff, David (NIH/NHLBI) [E] (b)(6)(b)(6)Cc: Chen, Helen Q. < (b)(6)Menetski, Joseph (FNIH) [T] < (b)(6)Alvarez, Rosa Maria Salathin, Carla < Parker, (b)(6)(b)(6)(b) (6) (b) (6) Ashley (NIH/OD) [E] < (b) (6)

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

We would like to have a meeting on Thursday with this team and the Antiviral review subteam to discuss and finalize the Antiviral Subgroup's selections from this latest Wave of prioritization.

Please let me know if you would be able to attend this meeting from 12-1pm ET.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/20/2020 2:10:26 AM Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange To: Eric Hughes | (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel | Colvis, (b) (6) Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Elliott Levy Vincent, Michael | Keith Gottesdiener [ (b) (6) (b)(6)Wung, Peter /US | (b) (6) ]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc] CC: Elizabeth Kim [ Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Salathin, Carla (b) (6) (b) (6) (b)(6)(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon ]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account (b) (6) Subject: Initial Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11 Attachments: ACTIV Therapeutics-Clinical AP Sub-Group Meeting 19May2020 Key Takeaways.pdf

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Thank you all for a productive meeting today. I am glad we were able to finalize the RFI/Survey for the companies. We are well into building the REDCap data capture platform. We will share with you all the link once it is done.

Thank you as well for your feedback on the mAbs. Many of you have already gotten back to me with nominations for the committee, so I will like follow up individually with those who have expressed interest and if we do not fully meet our 6-8, I will then reach out again to the broader group.

For your reference, please find attached the high level notes for the meeting. The formal complete summary will be sent tomorrow.

Thanks, Stacey

Stacey J. Adam, PhD Director, Cancer Research Partnerships

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Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 5/14/2020 12:13:17 AM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra Eisner, Mark | (b) (6) (b)(6)Gottesdiener, Keith (b)(6)Hughes, Eric | (b) (6) **Judy Currier** [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth (b) (6) LaVange, Lisa | Levy, Elliot I (b) (6) Mellors, John W (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep [ (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | Peppercorn, Amanda [ Poole, Mike (b) (6) (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) I/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn Garner, Carl Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Kurilla, Michael (NIH/NCATS) [E] Jansen, Kathrin (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina (b) (6) Demarcus | (b)(6)Macone, Erin (b)(6)Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6)

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Subject: ACTIV TX-Clinical Working Group #6

Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group\_14May2020 Meeting Guide.pdf

Location: https://fnih.zoom. (b) (6)

Start: 5/14/2020 6:00:00 PM End: 5/14/2020 7:00:00 PM

Show Time As: Tentative

Required Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Attendees: Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;

Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E];

Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]

Optional Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas Attendees: (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy

(NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ( (b) (6)

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention</a>

Looking forward to tomorrow's call.

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Thanks,
Stacey
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US (Tacoma) US (Houston) US (San Jose) From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent: 6/10/2020 9:08:03 AM

To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Anderson, James (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]

Subject: Fwd: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Attachments: image001.jpg; ATT00001.htm; image002.jpg; ATT00002.htm; image003.jpg; ATT00003.htm; image004.jpg;

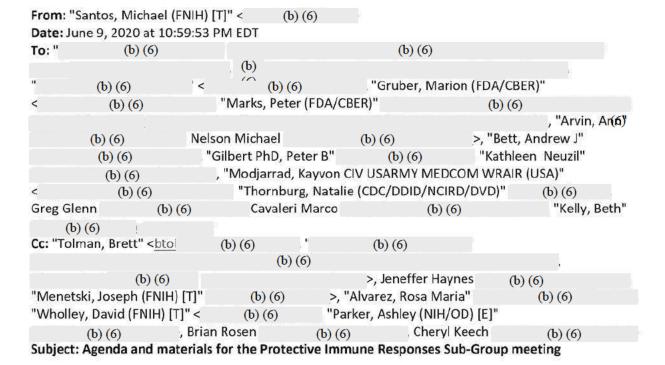
ATT00004.htm; Assay WG Tracker \_ Updated 6-4.xlsx; ATT00005.htm

Forwarding the information for the vaccines subgroup meeting taking place at 2:30pm today "inter-comparability of immunogenicity assays and centralized labs" and follow up conversations with Janet next week on assay development by vaccine developers — FYI.

Seems there are already POCs for NIAID.

Best, Ashley

#### Begin forwarded message:



Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards, Brett and Mike

#### Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, June 3, 2020 11:30 PM

Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards, Brett and Mike

#### Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Monday, June 1, 2020 1:04 PM

Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow

(Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards, Brett and Mike

#### Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Thursday, May 28, 2020 12:57 PM

Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- · Potential signals of human immunity:
  - o Develop specifics of what we are looking for from immunology research
  - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
  - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
  - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards, Brett and Mike

#### Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM

Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards, Brett and Mike

### Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Tuesday, May 26, 2020 12:19 AM

Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards, Brett and Mike

#### Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T] Sent: Tuesday, May 19, 2020 8:56 AM

Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- · An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards, Brett and Mike

# Michael Santos, PhD

Associate Vice President, Science

# Foundation for the National Institutes of Health

(b) (6) | fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] Sent: 5/19/2020 1:16:52 AM To: Vincent, Mike (b) (6) : Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bascles, Lionel [ ]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Corey, Larry Desrosiers, Betsy | (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensi]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura Srinivasan, Badhri | Wachtel, Jonathan (b) (6) (b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm] CC: Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Kenny, Dermot ]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]; Garner, Carlos Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric ]; Jansen, Kathrin [ (b)(6)Lowy, Douglas (NCI) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsal; Young, John Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret Carluccio, Dana Melencio, Cheryl (FNIH) [T] (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy ]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Criffield, Robin (b) (6) Hamilton, Nancy Minnich, Beth (b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Stratton, Benjamin

(b) (6)

Tolman, Brett | (b) (6) ]; Victoria Davey [/o=ExchangeLabs/ou=Exchange

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Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da];

Jintanat Ananworanich

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda\_05192020.pdf

(b)(6)

Location: https://zoom (b) (6)

Start: 5/19/2020 1:00:00 PM End: 5/19/2020 2:00:00 PM

Show Time As: Tentative

Recurrence: Weekly

every Tuesday and Friday from 9:00 AM to 10:00 AM

Required Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim

Attendees: (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema

(NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Wachtel,

Jonathan; Qashu, Felicia

Optional Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gail (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine

Attendees: (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John;

Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] ( (b) (6) Francis Collins; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuvesson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] ( (b) (6) Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat

Ananworanich

Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response; later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards, Karen

Karen H. Tountas, PhD Scientific Program Manager

Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/30/2020 12:30:54 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner Keith Gottesdiener I Eric Hughes (b) (6) (b)(6)(b) (6) LaVange, Lisa M | (b)(6)Elliott Levy (b)(6)Sandeep Menon | (b)(6)Amanda Peppercorn | (b)(6)Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn (b)(6)Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael (b) (6) Wung, Peter / US [ Karen Lynn Price (b) (6) Pamela Tenaerts, M.D. | (b) (6) (b)(6)CC: Macone, Erin | Mary Biggs (b) (6) Demarcus | (b)(6)(b)(6)Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan Elizabeth Kim | (b) (6) ]; Parker, Ashley (NIH/OD) [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: ACTIV TX-Clinical Therapeutics Master Protocol Subgroup #14 Location: https://fnih.zoom.us/ (b)(6)Start: 5/8/2020 5:00:00 PM End: 5/8/2020 6:00:00 PM Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.

Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley

Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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From:

Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]

Sent:

5/14/2020 2:52:17 PM

To:

CC:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Marks, Peter (FDA/CBER)

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Lane, Cliff (NIH/NIAID)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane] Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lowy, Douglas (NIH/NCI)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]

Subject:

RE: ChAdOx1

I don't sense that other companies have any major concerns. Merck, JJ, Sanofi – all part of good productive discussion. But Pfizer's two representatives spoke more than all the other companies combined for this particular hour call.

I'd ask Dough to give his perspective here.

From: Collins, Francis (NIH/OD) [E] < (b)(6)Sent: Thursday, May 14, 2020 10:32 AM To: Mascola, John (NIH/VRC) [E] < (b)(6)Marks, Peter (FDA/CBER) < (b)(6)Lane, Cliff (NIH/NIAID) [E] < (b) (6) Cc: Fauci, Anthony (NIH/NIAID) [E] < (b)(6)Wholley, David (FNIH) [T] < (b)(6)Tabak, Lawrence (NIH/OD) [E] < Parker, Ashley (NIH/OD) [E] < (b)(6)(b)(6)Lowy, Douglas (NIH/NCI) [E] < (b) (6)

Subject: RE: ChAdOx1

Thanks for this input, John and Peter.

It's too bad that Pfizer is dominating the discussion about the DSMB, when they apparently don't intend to take part in the harmonized master protocol anyway. Are there other companies represented on the Vaccines WG who might feel differently? I'm looping in Doug (and should have done so earlier, sorry!).

#### Francis

From: Mascola, John (NIH/VRC) [E] (b)(6)Sent: Thursday, May 14, 2020 9:03 AM To: Marks, Peter (FDA/CBER) >; Collins, Francis (NIH/OD) [E] < (b) (6) (b)(6); Lane, Cliff (NIH/NIAID) [E] < (b) (6) (b)(6)Cc: Fauci, Anthony (NIH/NIAID) [E] < (b) (6) : Wholley, David (FNIH) [T] Tabak, Lawrence (NIH/OD) [E] < (b)(6)>; Parker, Ashley (NIH/OD) [E] (b) (6)

Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) – took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter	(b) (6)				
Sent: Thursday, May 14, 2	020 6:23 AM				
To: Collins, Francis (NIH/O	D) [E] <	(b) (6)	Mascola, John (NIH/VRC) [E]	(b) (6)	>; Lane,
Cliff (NIH/NIAID) [E] <	(b) (6)				
Cc: Fauci, Anthony (NIH/N	IAID) [E]	(b) (6)	>; Wholley, David (FNIH) [T]	(b) (6)	>; Tabak,
Lawrence (NIH/OD) [E]	(b) (6	5)	Parker, Ashley (NIH/OD) [E]	(b) (6)	
Subject: DE: ChAdOv1					

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that	(b) (5)
(b) (5)	

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Happy to discuss

further.

Best Regards, Peter From: Collins, Francis (NIH/OD) [E] < (b)(6)Sent: Thursday, May 14, 2020 5:38 AM To: Mascola, John R (NIH) Marks, Peter (b)(6)>; Lane, Henry C (NIH) (b)(6)(b)(6); Wholley, David N (NIH) Cc: Fauci, Anthony S (NIH) (b)(6)(b)(6); Tabak, Lawrence A (NIH) (b) (6) >; Parker, Ashley S (NIH) (b)(6)

Subject: ChAdOx1

#### Gentlemen:

I need to know the update on where we are with Oxford, A-Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD] Sent: 4/9/2020 5:28:03 PM Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group To: (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [ (b) (6) Bright, Rick | (b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Disbrow, Gary (OS/ASPR/BARDA) [ (b)(6)Dolsten, Mikael (b)(6)Erbelding, Emily (NIH/NIAID) [E] [ James, Stephanie (FNIH) (b)(6)(b)(6)Marks, Peter (FDA/CBER) [T] | (b)(6)Lane, Cliff (NIH/NIAID) [E] | (b)(6)Marston, Hilary (NIH/NIAID) [E] [ Mascola, John (NIH/VRC) [E] (b)(6)(b) (6) Meeker, David | Menetski, Joseph (FNIH) [T] (b) (6) (b) (6) (b) (6) Pao, William | (b)(6)Paul, Steve I Perlmutter, Roger (b) (6) Rasi, Guido (b)(6)Plump, Andy [ (b) (6) (b) (6) Reed, John (b)(6)Rouse, Doris (b) (6) Santos, Michael (FNIH) [T] | Stein, Peter (FDA/CDER) Stoffels, Paul (b)(6)(b)(6)Tabak, Lawrence (NIH/OD) [E] | Tsai, John (b)(6)(b)(6)Vessey, Rupert I Woodcock, Janet (b)(6)Virgin, Skip | (b) (6) (b)(6)(FDA/CDER) | Young, John Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) (b) (6) Gladman, Jordan (NIH/OD) [E] (b)(6)Colvis, Christine (NIH/NCATS) [E] Desrosiers, Betsy | Hughes, Eric (b)(6)(b)(6)Hudson, Thomas Jansen, Kathrin | (b)(6)(b) (6) Kurilla, Michael (NIH/NCATS) [E] | Lowy, Douglas (NCI) (b) (6) (b) (6) Read, Sarah (NIH/NIAID) [E] [ Johnson, Robert (OS/ASPR/BARDA) (b) (6) (b)(6)(b)(6)Pandya, Hitesh | (b)(6)Skovronsky, Daniel (b)(6)Freire, Maria (FNIH) [T] (b)(6)(b)(6)Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene (b)(6)Barasch, Kimberly (NIH/NIAID) [C] [ CC: Conrad, Patricia (NIH/NIAID) [E] (b)(6)(b)(6)Hoffstetter, Renata (FNIH) [T] [ (b)(6)Iberdemaj, Vaide Melencio, Cheryl (FNIH) [T] [ Protasiewicz, Ann (b)(6)(b)(6)Wood, Gretchen ]; Thomas, Ashley (FDA/CDER) [ (b)(6)(b)(6)(NIH/OD) [E] [ Burrus-Shaw, Cyndi (NIH/OD) [E] [ Simon, Dina (b) (6) (b)(6)(NIH/OD) [C] [ (b) (6) Lagos, Enrique (NIH/NCATS) [E] [ (b)(6): McManus, Ayanna (NIH/OD) [E] [ Adam, Stacey (FNIH) [T] | Li, Rose (b)(6)(b)(6)Tountas, Karen (FNIH) [T] | (b)(6)(b)(6)Zottoli, Jessica Gonzalez, Nina [ Anderson, Margaret (b)(6)(b)(6)Robert Plenge Stratton, Ben | (b)(6)(b) (6) (b) (6) Alvarez, Rosa (b)(6)Kim, Elizabeth [ (b)(6)Wachtel, Jonathan Mammen, Mathai [JJCUS] Tolman, Brett | (b)(6)(b)(6)(b)(6)Lowy, Douglas (NIH/NCI) [E] [ (b)(6)Giorgi Sara FNIH Central Account | Lucas Smalldon (b)(6)(b) (6) Tierney, Julia (FDA/CBER) Sepulveda, Dorina (b)(6)(b) (6) (FNIH) [T] (b)(6)Subject: ACTIV response partnership leadership team meeting #2 Location: https://zoom.us. (b)(6)Start: 4/22/2020 2:00:00 PM End: 4/22/2020 3:00:00 PM

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# Required Attendees:

Austin, Christopher (NIH/NCATS) [E]; Bright, Rick; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; James, Stephanie (FNIH) [T]; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Hudson, Thomas; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Johnson, Robert (OS/ASPR/BARDA); Pandya, Hitesh; Skovronsky, Daniel;

# Optional Attendees:

Freire, Maria (FNIH) [T] (b) (6) (b) (6) Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Li, Rose; Tountas, Karen (FNIH) [T]; Zottoli, Jessica; Gonzalez, Nina; Anderson, Margaret; Robert Plenge; Stratton, Ben; Alvarez, Rosa; Kim, Elizabeth; Wachtel, Jonathan; Tolman, Brett; Mammen, Mathai [JJCUS]; Lowy, Douglas (NIH/NCI) [E]; Giorgi Sara; FNIH Central Account; Lucas Smalldon; Tierney, Julia; Sepulveda, Dorina (FNIH) [T]

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] Sent: 4/15/2020 9:27:45 PM To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-imascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdbe4598a57b423d484dcf9f-offit.email]; HSchuite@its.jnj.com; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccba4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) CC: Tolman, Brett [ (b) (6) Kozlowski, Mary (NIH/NCI) [C] (b) (6) 1; [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) (b) (6) (b) (6) (b) (6) Corrigan, Angela (NIH/VRC) [F] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83998896b0ce4d23a9e481d87568d20f-corriganar]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen [NIH/OD] [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group] (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy Kurilla, Michael (NIH/NCATS) [E] Hughes, Eric (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; (b) (6) ]; Arvin, Ann Wachtel, Jonathan [ (b) (6) (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Anderson, Margaret

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	Mascola, John (NIH/VRC) [E		(CDC/DDID	/NCIRD/OD); Offit, Pai	ıl; (b) (6)	Seals,
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	(FNIH) [T]; Tountas, Karen ( Betsy; Hughes, Eric; Kurilla, (b) (6)	Michael (NIH/NCATS) (b)		Sarah (NIH/NIAID) [E];		z, Nina;
	Margaret; Marston, Hilary	(NIH/NIAID) [E]				
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD)

Sent:

5/29/2020 11:40:46 PM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]

CC:

Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];

Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Freire, Maria (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Subject:

RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

From: Collins, Francis (NIH/OD) [E] < (b)(6)

Sent: Friday, May 29, 2020 5:59 PM

To: Wholley, David (FNIH) [T] <

(b) (6)

(b) (6)

Cc: Adam, Stacey (FNIH) [T] < (b)(6)

Freire, Maria (FNIH) [T] < Parker, Ashley (NIH/OD) [E] <

(b) (6) Gonzalez, Nina

(b)(6)

Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note - has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] < (b)(6)

Sent: Friday, May 29, 2020 1:59 PM

To: Collins, Francis (NIH/OD) [E] < (b) (6)

Cc: Adam, Stacey (FNIH) [T] (b) (6) Freire, Maria (FNIH) [T] < (b) (6) Gonzalez, Nina

: Parker, Ashley (NIH/OD) [E] < (b) (6) (b) (6)

Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

#### Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a

commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a portfolio approach to addressing the dramatic health and economic
  challenges posed by the pandemic, with harmonized efforts that address both disease etiology and
  symptomology.
  - ACTIV Baricitinib (ACTT2, sponsored by NIAID) in progress
  - ACTIV hiVIG (sponsored by NIAID) in progress
  - ACTIV-1 Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) (Phase III) ready to launch late June
  - ACTIV-2\*— Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
  - ACTIV-3\* Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
  - ACTIV-4 Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually,
     Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) (Phase II/III) –
     projected launch late June
  - ACTIV-5 De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) similar design to the mAb protocols, networks/sites/agents in discussions now projected launch August (if needed; i.e. if agents are not incorporated into mAb protocols)
     \* current priority
    - [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
  - Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
  - Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
     [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
  - Prioritization and Protocol Design: Who is Involved two-box slide containing names and affiliations of those involved in the Proritization and MP Subgroups (quality folks!)
  - ACTIV-1 Protocol for immunomodulators
    - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
    - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
    - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials
       = high POS
    - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
    - Companies have agreed to share data + common control arm+ common endpoints + DSMB =
      efficiency and ability to compare results across arms (this does not happen if companies test
      separately)
    - Protocol is 80% complete
      - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
        - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
      - All three companies have written their sections of the protocols, which are being merged into the master design
    - Working with OWS/BARDA on choice of CRO to run the trial;
- (b)(5)

"ACTIV-4" Protocol for anticoagulants

- Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS "network of networks" with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP From: (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/15/2020 7:21:22 PM To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner (b) (6) Keith Gottesdiener I (b) (6) Eric Hughes (b)(6)Elliott Levy (b) (6) LaVange, Lisa M | (b) (6) Sandeep Menon | Amanda Peppercorn [ Proschan, Michael (b)(6)(b)(6)(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Vincent, Michael Wung, Peter /US I Karen Lynn Price (b) (6) (b) (6) ]; Pamela Tenaerts, M.D. [ (b) (6) Patterson, Amy (NIH/NHLBI) [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy Beumont-Mauviel, Maria [JRDUS] [ i.com]; Peeters, Monika [JRDBE] (b) (6) (b) (6) Woodfall, Brian [JRDUS] [ (b)(6)(b) (6) Van Heeswijk, Rolf [JRDBE] ]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Bharucha\_David (b) (6) Gavin, Brian | (b) (6) Sadeh, Jonathan Harler, Mary Beth [ Goff, David (NIH/NHLBI) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc] CC: (b) (6) Demarcus | (b) (6) Macone, Erin (b)(6)Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan : Elizabeth Kim | Parker, Ashley (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina (b)(6)Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] [ (b) (6) Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20

Attachments: ACTIV\_Therapeutics Clinical Master Protocol Sub Group\_22May2020 Meeting Guide.pdf; Agenda capture 1.PNG

Location: https://fnih.zoom. (b) (6)

Start: 5/22/2020 6:00:00 PM End: 5/22/2020 6:30:00 PM

Show Time As: Busy

Required Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo

Attendees: (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne

(FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters,

Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Brown, Jeremy (NIH/NINDS) [E];

Bharucha\_David; Gavin, Brian; Sadeh, Jonathan; Harler, Mary Beth

Optional Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley Attendees: (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Melsheimer, Rich [CNTNL]

Dear ACTIV TX-Clinical Master Protocol Subgroup,

For this meeting today, we have decide to split this meeting into two meetings to make most efficient use of everyone's time. This first 30 minute meeting will be the entire group with the companies for ACTIV-1 to discuss the next steps for this protocol. The second 30 minutes will now become a meeting of the mAb Steering Committee to finalize some decisions for the ACTIV-2 protocol that need to be completed by EOD today.

Thanks for your understanding.

Please find attached the slides for this first meeting today.

Thanks, Stacey

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From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]

Sent: 5/30/2020 4:06:41 PM

To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Hallett, Adrienne (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa] Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]

Subject: Fwd: STAT News article: Human Challenge Trials

FYI

CC:

Renate Myles Deputy Director for Public Affairs Office of Communications and Public Liaison National Institutes of Health

(b)(6)

From: Gorman, Greta (FNIH) [T] < (b) (6)

Sent: Friday, May 29, 2020 5:48 PM To: Myles, Renate (NIH/OD) [E] Cc: Meltzer, Abbey (FNIH) [T]

Subject: FW: STAT News article: Human Challenge Trials

Hi Renate,

FYI. We are not going to respond to this person. Just keeping you in the loop.

Best, Greta

From: Santos, Michael (FNIH) [T] < (b) (6)

Sent: Friday, May 29, 2020 4:14 PM

To: Gorman, Greta (FNIH) [T] < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Freire, Maria (FNIH)

[T] < (b) (6)

Cc: Meltzer, Abbey (FNIH) [T] < (b) (6) James, Stephanie (FNIH) [T] < (b) (6)

Subject: FW: STAT News article: Human Challenge Trials

Hi Greta, David, Maria,

An email was sent from someone at the main pro-human challenge model study organization to the entire Vaccines Working Group and a bunch more people (you can see the long To and CC lists below). Someone clearly leaked an email to them that they pulled the addresses from. It's not immediately clear whether our draft manuscript was also leaked to them, but I think we can assume that it was. I have not circulated the submitted manuscript to the WG yet because I was worried about it being leaked ahead of publication.

There's nothing especially problematic with the email below or with the STAT article. They are more optimistic on timeline than we are, and more comfortable with exposing people to unknown risks, but in a reasonably argued way.

My default action here is no response of any kind. But of course I would appreciate your advice on what, if anything, we should do.

(Related: I have asked our manuscript writing team to update us as soon as they hear back from NEJM. No word yet.)

# Thanks,

Mike

#### Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

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Subje	ct: STAT News	article: Hum	an Challenge	Trials						

Dear Dr. Santos,

I thought your colleagues on the ACTIV Vaccine Working Group might be interested in this STAT News article that was published yesterday by my co-founder, Josh Morrison, entitled "Challenge trials can speed development of a Covid-19 vaccine. Planning for them needs to start now."

https://www.statnews.com/2020/05/28/challenge-trials-speed-development-covid-19-vaccine-start-planning-now/

As of May 29, 2020, 26,000+ volunteers from over 100 countries have signed up to participate in human challenge studies to advance the development of a safe and effective SARS-CoV-2 vaccine. While we agree that the utility of challenge trials is not a foregone conclusion, there is no

question that they have enormous potential value. As such, all of us at  $\underline{1Day\ Sooner}$  believe that planning for challenge trials should start now.

We have identified a number of funders interested in supporting the viral GMP phase of challenge trial preparations—and if anyone is aware of potential manufacturers for this endeavor (now that Ology has been awarded a Department of Defense contract and thus does not have capacity), we would appreciate any connections you may be able to facilitate.

Kind Regards, Sophie Co-Founder at 1Day Sooner Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] 7/16/2020 2:46:35 PM Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaal; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan\_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark (b) (6) Gottesdiener, Keith Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth LaVange, Lisa (b) (6) Levy, Elliot [ (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda [ (b) (6) Poole, Mike Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange (b)(6)Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Amanda Peppercorn Garner, Carl Koroshetz, Walter (NIH/NINDS) [E] (b)(6)(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94addd3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6)

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Subject:	<b>ACTIV Therapeutics-</b>	Clinical Working Gr	oup Meeting									
Attachments:	ACTIV_TX-Clinical_V		(C)	16.pdf								
Location:	https://fnih.zoom.		(b) (6)									
Start:	7/16/2020 5:00:00 F											
End:	7/16/2020 6:00:00 F	M										
Show Time As:	Tentative											
Recurrence:	Weekly											

every Thursday from 1:00 PM to 2:00 PM

GADB0000002842-2517559

# Required Attendees:

Higgs, Elizabeth (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ( (b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

## Optional Attendees:

Bethany Stokes; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA)

Dear ACTIV TX-Clinical WG,

Please find attached the slides with the agenda for today's meeting. As requested, we will be receiving an update from the Vaccine's WG as part of the meeting today.

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Thanks,
Stacey
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Join Zoom Meeting
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]

Sent:

7/30/2020 1:52:42 AM

To:

Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E]

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher

(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E]

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonim]; Parker, Ashley

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]

CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]

Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Stacey said there is collection of samples for genetic characterization in ACTIV-3. Copying her for clarification.

From: Lane, Cliff (NIH/NIAID) [E] < (b) (6)

Sent: Wednesday, July 29, 2020 6:20 PM

 To:
 Wholley, David (FNIH) [T] <</th>
 (b) (6)
 Collins, Francis (NIH/OD) [E] 
 (b) (6)
 Freire, Maria

 (FNIH) [T] 
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 Austin, Christopher (NIH/NCATS) [E] 
 (b) (6)
 Tabak, Lawrence (NIH/OD)

 [E] 
 (b) (6)
 Anderson, James (NIH/OD) [E] 
 Parker, Ashley (NIH/OD) [E]

 (b) (6)

Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

I am not aware of plans to do any genomics in ACTIV-3 as written. My guess it a similar situation for ACTIV-2. One could do amendments to add genomics but I am not advocating that approach given the time/complexity it would add. As noted, we have large observational cohort studies looking at genomics. I think it is something we could ask Team 2 to evaluate in the context of the treatment studies.

Cliff

From: "Wholley, David (FNIH) [T]" < (b) (6)

Date: Wednesday, July 29, 2020 at 5:58 PM

To: "Collins, Francis (NIH/OD) [E]" (b) (6) , "Freire, Maria (FNIH) [T]" < (b) (6)

"Austin, Christopher (NIH/NCATS) [E]" < (b) (6) "Lane, Cliff (NIH/NIAID) [E]"

< (b) (6) Lawrence Tabak < (b) (6) "Anderson, James (NIH/OD) [E]"

(b) (6) "Parker, Ashley (NIH/OD) [E]" (b) (6

Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Francis, I composed the following reply to Robert for your consideration. I'm happy to send it (he wrote to both of us) or you can; feel free to edit of course in either case. Cliff, please weigh in on how I have characterized the NIAID study you mentioned this morning. Thanks

Hi Robert:

Point taken. As always, we have to balance the benefits associated with genetic testing vs. the burden on sites of collection and banking and the need to make sure our trials are progressing as rapidly as possible. ACTIV-3 and ACTIV-4 are indeed planning to collect material for genetic testing from a reasonable subset of participants. ACTIV-1 does not have that in plan at this point, but may be willing to consider a substudy at more high functioning sites. This would be a hard sell for ACTIV-2, of course, as it is an outpatient cohort. FYI, NIAID is also planning a fairly large observational study that will include genetic analysis. Please let me know if you have other thoughts.

Regards, David

From: Collins, Francis (NIH/OD) [E] < (b)(6)Sent: Wednesday, July 29, 2020 7:43 AM Wholley, David (FNIH) [T] To: Freire, Maria (FNIH) [T] < >; Austin, Christopher (b) (6) (NIH/NCATS) [E] (b)(6); Lane, Cliff (NIH/NIAID) [E] Tabak, Lawrence (NIH/OD) (b) (6) ; Anderson, James (NIH/OD) [E] >; Parker, Ashley (NIH/OD) [E] [E] (b)(6)(b)(6)< (b) (6)

Subject: FW: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

From: Plenge, Robert < (b) (6)

Sent: Wednesday, July 29, 2020 7:33 AM

To: Wholley, David (FNIH) [T] (b) (6) Collins, Francis (NIH/OD) [E]

Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data (<u>here</u>, <u>here</u>, <u>here</u>, <u>here</u>), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

(b)(6)

From: "Melencio, Cheryl (FNIH) [T]" (b)(6)on behalf of "Wholley, David (FNIH) [T]" (b) (6) Date: Tuesday, July 28, 2020 at 10:55 PM To: "Austin, Christopher (NIH/NCATS) [E]" < "Bancel, Stephane" (b)(6)"Cavaleri, Marco" (b) (6) "Carter, Kara" < (b)(6)< "Cihlar, Tomas" "Collins, Francis (NIH/OD) < (b)(6)(b)(6)[E]" < "Corey, Larry" < "Culp, Michelle (NIH/OD) [E]" (b)(6)(b) (6) , "Disbrow, Gary (OS/ASPR/BARDA)" < (b) (6) (b) (6) , "Dolsten, Mikael" < "Erbelding, Emily (NIH/NIAID) [E]" "Erck, Stan" < (b) (6) (b)(6), "Fauci, Anthony (NIH/NIAID) [E]" < (b) (6) "Freire, Maria (FNIH) [T]" (b) (6) (b) (6) "Gadbois, Ellen (NIH/OD) [E]" , "Gibbons, Gary (NIH/NHLBI) [E]" (b)(6)"Hudson, Thomas" < (b)(6)(b) (6) "James, Stephanie (FNIH) [T]" < (b) (6) "Johnson, Robert (OS/ASPR/BARDA)" (b)(6), "Kramer, Lynn" < "Lepore, John" (b)(6)"Lane, Cliff (NIH/NIAID) [E]" < (b)(6)(b) (6) "Marks, Peter (FDA/CBER)" < . "Marston, Hilary (b)(6)(NIH/NIAID)[E]" <(b) (6) "Mascola, John (NIH/VRC) [E]" (b)(6)"Meeker, David" < (b)(6)"Menetski, Joseph (FNIH) [T]" < (b)(6)"Messonnier, Nancy (CDC/DDID/NCIRD/OD)" < , "Pandya, Hitesh" (b) (6) , "Pangalos, Mene" (b)(6)"Pao, William" < (b) (6) , "Paul, Steve" (b)(6)"Parker, Ashley (NIH/OD) [E]" (b) (6) , "Perlmutter, Roger" < (b)(6)"Plenge, Robert" (b) (6)

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                          "Plump, Andy" <
                                                                          Rachel Ramoni
                           "Rasi, Guido"
                                                     (b)(6)
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                          "Reese, David" <
                                                    (b) (6)
                                                                   "Rouse, Doris" <
                                                                                        (b) (6)
                                                                                                  "Santos,
                                          "Skovronsky, Daniel"
Michael (FNIH) [T]" <
                            (b) (6)
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                                                                                                 "Stein, Peter
(FDA/CDER)"
                                          "Stoffels, Paul" <
                                                                                  , "Tabak, Lawrence (NIH/OD)
                         (b) (6)
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[E]" <
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                                 "Talley, Michael" <
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                                                                                "Tsai, John"
                           "Vessey, Rupert" <
                                                                       "Virgin, Skip" <
           (b) (6)
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"Wholley, David (FNIH) [T]"
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                                                                               , "Colvis, Christine (NIH/NCATS)
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                                  "Young, John" <
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                                                                                        >, Eric Hughes
                              "Desrosiers, Betsy"
[E]"
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                              "Jansen, Kathrin" <
                                                             (b) (6)
                                                                               . "Kurilla, Michael (NIH/NCATS)
<
[E]"
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                              , "Lowy, Douglas (NCI)" <
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                                                                        . "Read, Sarah (NIH/NIAID) [E]"
                        , "Young, John"
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                                                                "Byrnes, Noni (NIH/CSR) [E]"
Cc: "Bianchi, Diana (NIH/NICHD) [E]" <
         (b) (6)
                       "Glass, Roger (NIH/FIC) [E]" <
                                                                           "Hodes, Richard (NIH/NIA) [E]"
                         , "Koob, George (NIH/NIAAA) [E]"
                                                                                    >, "Koroshetz, Walter
          (b)(6)
                                                                     (b) (6)
(NIH/NINDS)[E]" <
                                                "Langevin, Helene (NIH/NCCIH) [E]"
                                                                      (b) (6)
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                            , "Norris, Andrea (NIH/CIT) [E]" <
                                                                                      "Perez-Stable, Eliseo
                                                 , "Rodgers, Griffin (NIH/NIDDK) [E]"
(NIH/NIMHD) [E]"
                               (b) (6)
                              "Schwetz, Tara (NIH/OD) [E]" <
                                                                                        "Sharpless, Norman
             (b)(6)
                                                                        (b) (6)
(NIH/NCI) [E]" <
                                            "Tucci, Debara (NIH/NIDCD) [E]" <
                                                                                         (b) (6)
                                                          >, "Volkow, Nora (NIH/NIDA) [E]"
"Tumminia, Santa (NIH/NEI) [E]"
                                          (b) (6)
                         "Woychik, Rick (NIH/NIEHS) [E]" <
                                                                      (b) (6)
                                                                                     "Adam, Stacey (FNIH) [T]"
          (b) (6)
                                                               , "Anderson, Margaret"
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                  "Alvarez, Rosa"
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                                                                            "Elsaid, Olivia"
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                                 "Chen, Helen" <
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                        "Gonzalez, Nina" <
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                                                                        "James, Stephanie (FNIH) [T]"
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                    "Menetski, Joseph (FNIH) [T]" <
                                                                        "Santos, Michael (FNIH) [T]"
                     "Stratton, Ben" <
                                                                 "Tolman, Brett"
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"Tountas, Karen (FNIH) [T]" <
                                               "Wachtel, Jonathan" <
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                                                                                                    "Wholley,
David (FNIH) [T]" <
                                     "Anderson, James (NIH/OD) [E]" <
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                                                  , "Castillejos, Carlos" <
"Burklow, John (NIH/OD) [E]" <
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                                                                                                     "Culp,
                                                  FNIH Central Account <
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Michelle (NIH/OD) [E]" <
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                                                                                                       "Freire,
Maria (FNIH) [T]"
                         (b) (6)
                                     , "Gadbois, Ellen (NIH/OD) [E]"
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                                                                                              , "Wolinetz,
Carrie (NIH/OD) [E]" <
                                               , "Burklow, John (NIH/OD) [E]"
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                                                >, "Hallett, Adrienne (NIH/OD) [E]"
"Gorman, Greta (FNIH) [T]"
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                           , "Meltzer, Abbey (FNIH) [T]"
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                                                                               , "Myles, Renate (NIH/OD) [E]"
           (b) (6)
         (b) (6)
                      "Melencio, Cheryl (FNIH) [T]" <
                                                                (b) (6)
Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference
Resent-From: <
                        (b) (6)
```

# [Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

Join Zoom Meeting

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Find your local number: https://fnih.zoom.
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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD) 5/13/2020 1:57:04 AM Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Dolsten, Mikael Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Pao, William Stoffels, Paul [JJCUS] [ Woodcock, Janet (FDA/CDER) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) : Hughes, Eric (b) (6) Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d] Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs] Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leaderhsip-vF 051220.pdf

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

From:

Sent:

To:

CC:

Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF] 10/16/2020 9:45:36 PM Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bfdfccfda71ced-jatkinso]; Chang, Soju (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99b3263e72a94bfa9ded3f82c4dae59c-changsoju]; (b)(6)'Gavin, Brian' 'Sadeh, Jonathan' (b) (6) (b) (6) (b) (6) 'Melsheimer, Rich [CNTNL]' [ 'Beumont-Mauviel, Maria [JRDUS]' [ (b) (6) (b)(6)'Bharucha David' | Eric (b) (6) 'Ferguson William' (b)(6)Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; 'LaVange, Lisa M' Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Gardner, Bobbi (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dd21d20185e4e46a20a6eb89c314580-gardnerbw]; 'Sandeep Menon' 'Yong, Florence H' 'Trank, Christina' (b) (6) (b) (6) (b)(6)'Kimmel, Bridget [JRDUS' 'Moyo, Vusi' (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Marti, Emily (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=970fb6ea63944699aa433fb034a0f63f-carlsone]; Eisnor, Derek (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae393740634d4ec9954494c0c2ef669a-Derek.Eisnol; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason] 'Montgomery, Stephanie' O'Sullivan Alexandra Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Neta Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d10b8fd5dff411eb1d6f8f4892e27e3-nnelson.tec]; Butler, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4782eaa72024479197826e3d71d5584c-sbutler.tec]; Daniel Benjamin Jr, M.D., Ph.D. [ (b)(6)Theresa Jasion (b) (6) Molina, Daniel Lind, Brian (NIH/NCATS) [E] (b)(6)Rose Beci | (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486ebcc6ebe34d08a691e66632ed5005-lindbj]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; O'rourke, Anna (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a43de8d7c474c538615405753ccfb6c-Anna.O rour]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Lori Hudson, Ph.D. "Huyen Cao" < ["Huyen Cao" < Huven (b) (6) (b) (6) (b)(6)Brody, Betty (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecad8c87c49d4f018bd2530beaf4a30d-Betty.Brody]; Chiang, Anna

From:

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To:

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(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=aa42127fa32b4d0fa0ccce5799cf419f-Anna.Chiang]; Schmidt, Jeffrey

(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=3431da5ab88f4204858d4c6fe19aaa7a-Jeffrey.Sch]

Subject: RE: 1st ACTIV-1 patient has been randomized

Terrific! I just talked about the study with Wolf Blitzer on CNN - it's great to have it underway.

Many thanks to all who worked so hard to get to this point. Onward!

### Francis

		(NIH/NCATS) [E] <	(b) (6)			
		16, 2020 4:48 PM (NIH/NCATS) [E] <	(b) (6)	Atkinson I	ane (NIH/NCATS	) [E]
<		Chang, Soju (NIH/N				/ [-]
<		'Gavin, Brian' <				(b) (6)
		VTNL]' < (b) (6)				
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<		Read, Sarah (N				
<		Proschan, Michael				
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<		<"Huyen Cao" <				(6) Brody, Be
		(b) (6)	Chiang, Anna (OS	S/ASPR/BARDA) <	(b) (6)	Schmidt, Jeffre
The control of the same		(b) (6)				
Subjec	t: 1st ACTIV-1 p	oatient has been randoi	mized			

### Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all! Sam B

**Sam Bozzette. MD, PhD**Chief Medical Officer
Immediate Office of the Director

National Center for Advancing Translational Sciences National Institutes of Health

6701 Democracy Blvd., Room 926 Bethesda, MD 20892 (Use ZIP code 20817 for overnight mail or courier)

Phone: (b) (6) E-mail: (b) (6)

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 1/12/2021 9:59:00 PM Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bancel, Stephane Carter, Kara (b) (6) Cavaleri, Marco (b) (6) Cihlar, Tomas | ]; Collins, Francis (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan ]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn ]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David ; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh (b) (6) Pangalos, Mene [ (b)(6)Pao, William (b)(6)Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Paul, Steve Perlmutter, Roger (b) (6) ]; Plenge, Robert [ (b) (6) Plump, Andy | Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Reed, John Reese, David Santos, Michael (FNIH) (b) (6) (b) (6) Rouse, Doris (b) (6) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel (b)(6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael (b) (6) Tsai, John (b) (6) Vessey, Rupert | (b) (6) Virgin, : Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John

From:

Sent:

To:

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Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
          (b) (6)
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
                               ]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin
                          ; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson
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Helen [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Connelly, Sarah
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab];
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mendelson, Jesse
                          Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact f12]; Stratton,
Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan
                                                                                   (b) (6)
Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana
               (b) (6)
                                    Castillejos, Carlos |
                                                           (b) (6)
                                                                        ]; FNIH Central Account
                          Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
          (b)(6)
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Lumsden, Joanne
(NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Myles, Renate (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Meltzer, Abbey (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly
(NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
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                         ]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfied, Anita
                                                 (b) (6)
                                                                 Conrad, Patricia (NIH/NIAID) [E]
          (b) (6)
                          Coan, Amanda
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne
(NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan
                       Fuhrer, Nicole |
                                                                Giorgi, Sara |
        (b)(6)
                                               (b) (6)
                                      Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
Hoban, Michelle
                       (b) (6)
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter];
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CC:

Iberdemaj, Vaide | Jenkins, Christine S. [ m]; Krack, (b)(6)(b) (6) Kimberly [kimberly]; (b)(6)Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan | (b)(6)Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Martin, Melisa [ McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth Perala, Mie | Protasiewicz, Ann (b) (6) (b) (6) (b)(6)Riccobene, Kim Riggin, Mary (b) (6) (b) (6) Schuster, Donna | Ripley, Nadege | (b) (6) (b)(6)Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy ]; Zottoli, Jessica ]; Hughes, Karen (NIH/OD) [E] (b)(6)[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin] ACTIV Leadership Team Call #16

Subject:

Location: https://fnih.zoom.u (b)(6)

Start: 5/28/2021 1:00:00 PM End: 5/28/2021 2:30:00 PM

Show Time As: Tentative

# Required Attendees:

Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim;

Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Magbie-Robinson, Kim

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Find your local number: https://fnih.zoom.us/
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From: Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CDCD432E986961F1548C5EC6-KOROSHETZW] Sent: 5/4/2020 1:21:51 AM To: Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Hughes (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli | Naimish Patel Colvis, Christine (NIH/NCATS) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael | Keith Gottesdiener I Elliott Levy (b) (6) (b) (6) Wung, Peter /US | Higgs, Elizabeth (NIH/NIAID) [E] (b)(6)(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner (b) (6) CC: Elizabeth Kim [ (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Salathin, Carla ]; Merritt, Gabriella Marie Romanowski, Jake (b)(6)(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon m]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam] Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Thanks very much John. Had a stupid question.

The drug was obviously built for HIV which requires activity throughout the body. Has anyone considered whether for COVID-19 a nebulized administration down the trachea into the lung would enable more potent effects given that is the site of first viral entry? Maybe enable higher doses without untoward effects.

Reason to consider checking this for other anti-virals given in early stages of the illness?

# Walter

From: Mellors, John W Sent: Sunday, May 3, 2020 4:05 PM To: Adam, Stacey (FNIH) [T] < Eric Hughes < Read, Sarah (NIH/NIAID) [E] (b)(6)(b) (6) Ruxandra Draghia-Akli < (b) (6) Naimish Patel < (b) (6) Colvis, Christine (NIH/NCATS) [E] < Young, John < Stein, Peter (b)(6)(b)(6)(FDA/CDER) < (b)(6)Poole, Mike < (b)(6)Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) Vincent, Michael < (b) (6) Keith Gottesdiener < Wung, Peter /US (b)(6)Elliott Levy < (b)(6)Higgs, Elizabeth Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) (b) (6) (NIH/NIAID) [E] < Carlos O Garner <garner (b)(6)

Cc: Elizabeth Kim <	(b) (6) Mene	etski, Joseph (FNIH)	[T] < (b)	(6) Salati	nin, Carla
< (b) (6)		lla Marie < (l		nanowski, Jake <	1270
Parker, Ashley (NIH/OD) [F		Wholley, Da			
(FNIH)[T] < (b)(6)	Lucas Smalld		(b) (6)		, Paula (NIH/NINDS)
Maria de la companya				Walker	, radia (Min/MinDS)
[E] < (b) (6)	Ward, Jackie (NII	27.67.15			
Subject: RE: Material for A	ACTIV Agent Prioritiza	tion wave I Final D	iscussion Meeti	ng	
Useful EMA review of remdes metabolism.	sivir. Substrate and wea	k inhibitor of CYP3A.	Not clear what the	effect of 3A4 inhib	itor would be of complex
From: Adam, Stacey (FNIH		(6)			
Sent: Sunday, May 3, 2020					
To: Eric Hughes <	(b) (6)	Read, Sarah (NIH/NI	AID) [E] <	(b) (6)	Ruxandra Draghia-
Akli < (b) (6)	Mellors, John W	< (b) (6)	Naimish Patel <	(b) (6	) Colvis,
Christine (NIH/NCATS) [E]	< (b) (6)	Young, John	< (b)	(6)	Stein, Peter
	) (6) Poole,		(b) (6)	Buchma	n. Tim
(OS/ASPR/BARDA) (CTR) <	We construct		7.5	(b) (6)	Keith
Gottesdiener <	(b) (6)		(b) (6)	Wung, Peter /l	
		(NIH/NINDS) [E] <			
< (b) (6)				пів	s, Elizabeth
	(b) (6) Carlos		(b) (6)	(0) 0.1.11	7000 ( <b>3</b> 000)
Cc: Elizabeth Kim <		tski, Joseph (FNIH)	7.55	Name of the Party	nin, Carla
< (b) (6)	Merritt, Gabrie	CONTROL DE LA CO	THE SHARE THE PROPERTY OF THE STATE OF THE S	nanowski, Jake <	
Parker, Ashley (NIH/OD) [8		Wholley, Da			The state of the s
(FNIH)[T] < (b)(6)	Lucas Smalld	on <	(b) (6)	Walker	, Paula (NIH/NINDS)
[E] < (b) (6)	Ward, Jackie (NII	H/NINDS) [E] <	(b) (6)		
Subject: Material for ACTI	V Agent Prioritization	Wave 1 Final Discu	ssion Meeting		
Hi ACTIV TX-Clinical Priorit	tization Subgroup me	mbers,			
				THE PERSON NAMED IN TAXABLE PARTY.	NORTH THOUSE AND STOP
Please find attached the fi		the agents that can	ne through triag	e in Wave 1. We	will use this
document for our discussi					
For those who sent me co	mments, I did not wa	nt to over whelm th	ne score sheet w	ill multiple rows	of
information. However, Ih	ave those and I will in	nclude them in the	final record for p	osterity for this	round. You can also
feel free to bring them up	during the discussion	if helpful to the gr	oup.		
Thanks,					
Stacey					
J. G.					
Stacey J. Adam, PhD					
Director, Cancer					
Research Partnerships	(b) (c)				
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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 4/30/2020 12:30:52 PM To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [ Butterton, Joan ]; Collins, Sylva (FDA/CDER) (b)(6)(b) (6) Judy Currier ]; De Claro, R. Angelo (FDA/CDER) (b)(6)(b) (6) Keith Gottesdiener (b)(6)Mark Eisner (b) (6) Eric Hughes | LaVange, Lisa M (b)(6)(b) (6) (b)(6)Elliott Levy [ Sandeep Menon | : Amanda Peppercorn (b)(6)(b)(6)(b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] [ Amanda Peppercorn | ]; Price, Dionne (b)(6)(b)(6)(FDA/CDER) | Rubin, Daniel B. (FDA/CDER) | Shen, Yuan Li (b) (6) (b)(6)(FDA/CDER) 1: Goff, David ]; Farley, John (FDA/CDER) (b)(6)(b)(6)(NIH/NHLBI) [E] I (b)(6)Vincent, Michael | (b)(6)Wung, Peter /US (b)(6)Karen Lynn Price [ Pamela Tenaerts, M.D. (b)(6)]; Koroshetz, Walter (NIH/NINDS) [E] [ (b)(6)(b) (6) CC: Mary Biggs [ Demarcus | Macone, Erin | (b)(6)(b) (6) (b)(6)Tountas, Karen (FNIH) [T] [ (b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim (b)(6)Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [ Melencio, Cheryl (FNIH) [T] (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [ Hoots, W. Keith (b)(6)(b)(6)(NIH/NHLBI) [E] [ ]; Patterson, Amy (NIH/NHLBI) [E] [ Chertow, (b) (6) (b) (6) Jessica (NIH/NHLBI) [E] Paltoo, Dina (NIH/NLM) [E] [ Gibbons, Gary (b)(6)(b) (6) (NIH/NHLBI) [E] | (b)(6)ACTIV TX-Clinical Master Protocol Subgroup Meeting #12 Subject: Attachments: ACTIV Therapeutics-Clinical MP Subgroup 4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting 4May2020 Agenda.pdf Location: https://fnih.zoom. (b) (6) Start: 5/4/2020 5:00:00 PM

End: 5/4/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Hoots, W. Keith (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Chertow, Jessica (NIH/NHLBI) [E]; Paltoo, Dina (NIH/NLM) [E]; Gibbons, Gary (NIH/NHLBI) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attach the materials for today's meeting.

- Agenda
- Slides

Thanks,

# Stacey

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Sent: 8/26/2020 1:49:02 AM

Subject: FW: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Attachments: 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pdf; 2020-07-

29\_ACTIV\_Leadership\_Team\_Meeting\_Summary final.pdf; 2020-08-14\_Executive\_Committee\_Meeting\_Summary

vFinal.pdf

		eryl (FNIH) [T] <		On Behalf Of	Wholley, Da	vid (FNIH) [T]	
To: A	Tuesday, Augu	st 25, 2020 9:47 PM ner (NIH/NCATS) [E] <	(1-) (6)	Dane	al Stanbana		
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5	(b) (	6) Car	ter, kara <	(6) (6)	Cav	aieri, iviarco	(OD) [E]
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		Paul, Steve <					
Pleng	ge, Robert <	(b) (6)	Plump, Andy <	(b)	(6)	Rachel Rame	oni
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<	(b) (6)	Rouse, Doris <	(b) (6) Sar	ntos, Michael	(FNIH) [T] <	(b) (6)	Skovronsky,
Danie	el <	(b) (6) St	ein, Peter (FDA/0	CDER) <	(b) (6)	Stoffe	ls, Paul
		Tabak, Lawrence					
							) Virgin, Skip
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<	(b) (6)	Lowy, Douglas	s(NCI) < (b)	(6) Rea	d, Sarah (NIF	I/NIAID) [E] <	(b) (6)
Youn	g, John <	(b) (6)					
Cc: A	dam, Stacey (FI	V(A) =	Alvarez, R	osa <	(b) (6)	Anderso	n, Margaret
	(b) (6)	Chen, He	elen < (1	b) (6)	Elsaid, Oli	ivia < (b)	) (6)
Gonz	alez, Nina <	(b) (6)	Hawk, Harris	son <	(b) (6)	Menetski, Jo	oseph (FNIH) [T]
		Santos, Michael (F					
			as, Karen (FNIH)			Wachtel, Jonat	
<	(b) (6)	Wholley, David	(FNIH) [T] <	(b) (6)	Anders	on, James (NIH/	OD) [E]
<	(b) (6)	Austin, Chr	istopher (NIH/NO	CATS) [E] <	(b) (6)	Burklo	w, John (NIH/OD) [E]
<	(b) (6)	Castillejos, Carlo			p, Michelle (	NIH/OD) [E]	
<	(b) (6)	FNIH Central Ad		(b) (6)		e, Maria (FNIH)	[T]
<	(b) (6)	Gadbois, Ellen (NIH/		(b) (6)		Adrienne (NIH/C	
<	(b) (6)		IH/NIAID) [E] <	(b) (6)		es, Renate (NIH,	
<	(b) (6)	Parker, Ashley (N		(b) (6)		ak, Lawrence (N	93
<	(b) (6)	and the state of t	rie (NIH/OD) [E]		0) (6)	The second secon	in (NIH/OD) [E]
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<	(b) (6)	Gorman, Greta (FNIH) [T] <	(b) (6)	Hallett, Adrienne	e (NIH/OD) [E]
<	(b) (6)	Meltzer, Abbey (FNIH) [T] <	(b) (6)	Myles, Rena	te (NIH/OD) [E]
<	(b) (6)	Wolinetz, Carrie (NIH/OD) [E] <	(b) (6)	Lucas S	malldon
<	(b) (6)	Villafana, Tonya <	<	(b) (6)	Brian Rosen
<	(b) (6)				

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

# Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E]; (b) (6) Eron, Joe; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Haggwiik, Balf (JRDBE); Mallare, John W.

[JRDUS]; Van Heeswijk, Rolf [JRDBE]; Mellors, John W

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr; Javan, Arzhang

(NIH/NIAID) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today's call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol.

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Thanks,
Stacey
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US (Houston) US (San Jose) From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH] Sent: 5/18/2020 12:22:03 AM To: Bascles, Lionel (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron\_cohen]; Corey, Larry Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Garner, Carlos Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-gashufm]; Resnansky, Laura Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative (b) (6) Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike ]; Weinmann, Gail (NIH/NHLBI) [E] (b)(6); Wachtel, Jonathan (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang] CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric Jansen, Kathrin Lowy, Douglas (NCI) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John Criffield, Robin | Hamilton, Nancy (b) (6) (b) (6) ]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Minnich, Beth Mueller-Reichenstein, Petra [ (b) (6) Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-picodf]; Quadros, Nora Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b) (6) (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Carluccio, Dana Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Heaton, Penny | (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li,

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Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

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(FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuvesson, Nancy

(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

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Subject: Summary and action items - CT Capacity WG meeting #8

Attachments: Clinical\_Trial\_Capacity\_Working\_Group\_Meeting\_9\_Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #9 (May 15, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, May 19 at 9 am eastern time USA.

Cheers!

Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

(b) (6) <u>fnih.org</u>

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Sent:	4/30/2020 12:54:05						
То:	Eric Hughes   (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli   (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative						
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CC:	Elizabeth Kim [	(b) (6)				eLabs/ou=Exchang	
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	Ward, Jackie (NIH/I						
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Subject:	ACTIV TX-Clinical Ag		on Subgroup				
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End:	5/5/2020 6:00:00 P						
Show Time As:		***					
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Find your local number: https://fnih.zoom.us

Sent:

9/24/2020 3:04:25 AM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Allen-Gifford, Patrice

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-allengiffor]

CC:

Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gladman, Jordan

(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]

Subject:

RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Attachments: 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pdf

Thank you, Francis.

Good morning Patrice,

I've made a few adjustments to the email to go out to the ICD ONLY list this morning – please see below.

Thanks, Ashley

To: ICD-ONLY-L@LIST.NIH.GOV

Cc: Wholley, David (FNIH) [T] <

(b) (6)

Melencio, Cheryl (FNIH) [T] <

(b)(6)

Bcc: Parker, Ashley (NIH/OD) [E]

(b)(6)

Dear Colleagues,

As discussed during our conference call yesterday, ICDs (principals only please; no surrogates or additional staff) are invited to join the virtual ACTIV leadership team meeting today August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you, Francis

From: Collins, Francis (NIH/OD) [E] <

(b)(6)

Sent: Wednesday, August 26, 2020 5:57 AM

To: Parker, Ashley (NIH/OD) [E] <

(b)(6)

Cc: Wholley, David (FNIH) [T] <

Melencio, Cheryl (FNIH) [T] < (b)(6)

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Gladman, Jordan

(NIH/OD) [E] <

(b) (6)

Allen-Gifford, Patrice (NIH/OD) [E] <

(b)(6)

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Be sure to change the text of the e-mail from "tomorrow" to "today".

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, August 26, 2020 5:56 AM

To: Parker, Ashley (NIH/OD) [E] <

(b)(6)

(b) (6)

Cc: Wholley, David (FNIH) [T] <

Melencio, Cheryl (FNIH) [T]

(b) (6)

; Gladman, Jordan

(NIH/OD) [E] < (b) (6) Allen-Gifford, Patrice (NIH/OD) [E] (b) (6) **Subject:** RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Yes, this note would be great. Looping in Exec Sec to ask that it be sent first thing this morning.

## Francis

From: Parker, Ashley (NIH/OD) [E] < (b) (6) >

Sent: Tuesday, August 25, 2020 10:52 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6) Gladman, Jordan (NIH/OD) [E] (b) (6)

Subject: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference Importance: High

Hi Francis,

To ensure the ICDs receive the information for the ACTIV LT meeting tomorrow – would you like to forward the following to the ICD only list. Below is a draft note for consideration.

To: ICD-ONLY-L@LIST.NIH.GOV
Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6)

Dear Colleagues,

As discussed during our conference call this afternoon, ICDs (principals only please; no surrogates or additional staff) are invited to join the virtual ACTIV leadership team meeting tomorrow August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you, Francis

	B R -				N. 65 5	
From: Melencio, Chery	l (FNIH) [T]	(b) (6)	On Behalf Of	Wholley, David (	FNIH) [T]	
Sent: Tuesday, August	25, 2020 9:47 PM					
To: Austin, Christopher	(NIH/NCATS) [E] <	(b) (6)	Bance	l, Stephane		
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<	(b) (6)								

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

# Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

Join Zoom Meeting
https://fnih.zoom.us

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley Senior Vice-President, Research Partnerships Foundation for the National Institutes of Health (b) (6)

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In 2019, the FNIH carned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
To:
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Beigel, John (NIH) [E]
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Culp, Michelle (NIH/OD) [E]
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Brown, Jeremy (NIH/NINDS)
              [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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**Start**: 9/10/2020 5:00:00 PM **End**: 9/10/2020 6:00:00 PM

Show Time As: Busy

Recurrence: (none)

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From:

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To:

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Subject: ACTIV Therapeutics-Clinical Working Group - Meeting #3

Location: https://fnih.zoom. (b) (6)

Start: 4/23/2020 6:00:00 PM End: 4/23/2020 7:00:00 PM

Show Time As: Tentative

Required Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Attendees: Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John;

Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH)

[T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva; Amanda Peppercorn

Optional Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas Attendees: (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla;

Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

This will be the 3<sup>rd</sup> meeting of the TX-Clinical WG. We will update the invite with more information before the meeting.

Thanks, Stacey

Join Zoom Meeting

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US (Chicago)

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+ (b) (6) US (New York) + (b) (6) US (Chicago)

+1 (b) (6) US (b) (6) US

+ (b) (6) US (Houston) + (b) (6) US (San Jose) + (b) (6) US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: https://fnih.zoom.us (b) (6)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]

Sent:

5/14/2020 2:19:48 PM

To:

Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Myles, Renate (NIH/OD) [E]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Kolberg, Rebecca (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]

CC:

Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Tabak, Lawrence (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T]

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH)

[T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]

Subject:

RE: JAMA Viewpoint on ACTIV: please review

To be clear the new WG members are on this email thread below but we will need to add them to draft webpage once we have permission to list their names.

+ Abbey.

Thanks, Ashley

 From: Parker, Ashley (NIH/OD) [E]

 Sent: Thursday, May 14, 2020 10:16 AM

 To: Collins, Francis (NIH/OD) [E] < (b) (6)</td>

 Myles, Renate (NIH/OD) [E] < (b) (6)</td>

 Kolberg, Rebecca (NIH/OD) [E] < (b) (6)</td>

 Tabak, Lawrence (NIH/OD) [E] < (b) (6)</td>

 Wholley, David (FNIH) [T] < (b) (6)</td>

 Melencio, Cheryl (FNIH) [T] < (b) (6)</td>

Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis.

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

To:

Cc: Myles, Renate (NIH/OD) [E] (b			(6)	y; Meltzer, Abb	pey (FNIH) [T]	(	g; Whol	lley, David
(FNIH) [T	(b) (6)					b		
Bcc: Stof	ffels, Paul	(b) (	(6)		Fauci, Aı	nthony (NI	H/NIAID) [E]	
<	(b) (6) Gibbons, Gary (N		H/NHLBI) [E] < (b) (6)		(b) (6)	(6) ; Pao, William		
(b) (6)		>; Woodcock, Janet (FDA/CDER) J			(b) (6)		(b) (6)	
	(b) (6)	≥; Arvin, Anr	n <	(b) (6)	Buchbin	der, Susan		
<	(b) (6)	; Corey, Larry	<	(b) (6)	Davis, M	lark	(b) (6)	>; Emini,
Emilio <	(	b) (6)	Hanor	n, Emmanuel <	(b)	(6)	; Haynes, I	Barton

(b) (6)	Hotez, Peter	(b) (6)	>; Jansen, Kat	hrin	(b) (6)	
Lanzavecchia, Antonio	(b) (6)	Lowy, D	ouglas (NIH/N	CI) [E] (1	o) (6)	>; Marks, Peter
Lanzavecchia, Antonio (FDA/CBER) <	(b) (6)	Mascola, John <	(b) (6)	) Mes	sonnier, Nan	су
(CDC/DDID/NCIRD/OD)	(b) (6)	Offit, Paul	(b) (6)	; Parker, A	shley (NIH/O	D) [E]
< (b) (6)						
Schuitemaker, Hanneke						
< (b) (6)						
Michael, Nelson,	(b) (6)	>; Adam,	Stacey (FNIH)	[T] (b) (6)	>; Basc	es, Lionel
< (b) (6)	; Cohen, My	ron <	(b) (6)	Corey, La	arry <	(b) (6)
Desrosiers , Betsy < (b)	) (6)	g Dio	ckens, Jim (NIH	/NCATS) [C] <	(b) (6)	;
< (b) (6) Desrosiers , Betsy < (b) Doroshow, James (NIH/	NCI) [E] (b	) (6) >;	Goff, David (N	IH/NHLBI) [E] <	(b) (6)	; Heaton,
Penny (b) (c	6) ; Kur	illa, Mike	(b) (6) ;	Nayak, Seema	(NIH/NIAID) [	E]
(b) (6)	; Parker, Ashley (N	VIH/OD) [E] <	(b) (6)	Payton,	Manzine	
(b) (6)	Resnansky, Lau	ura <	(b) (6)	Srinivasan,	Badhri	Impassab (mr)
(b) (6)	>; Stein, i	Peter (FDA/CDEI	K) <	(b) (6)	Karen	(FNIH)[I]
(b) (6) ; V Woodcock, Janet (FDA/ (NIH/FIC) [E] <	CDED	(b) (6)	;>; vva	chtel, Jonathan	(b)	(6)
(NULL/EIC) [E]	CDERIC	(b) (b)	(L) (L)	(b) (b)	Sizemore	Christine
(INIT/FIC/[E] <	(D) (D)	Victoria Davey	y < (b)	(6) Qa	isnu, rencia (	VIII/OD) [E]
(b) (6) Adam, Stacey (FNIH) [T]	, weiminann,	(b) (6)	, IVIE (NILL/NICATS)	insan,	(b) (6)	Puchman Tim
(OS/ASPR/BARDA) (CTR	(b) (6)	Butter	ton loan	(P) (Q)	(0)	Turrier Judy
	; De Claro, R.					
(b) (6)	> Fisner Mark <	(b) (6)	Garne	(0) (0) er.	Diagii	ia Akii, Kazariara
Carlos (b) (6)	>Gotteso	diener Keith	(b) (6	5)	· Hughes Fri	c
(b) (6)	Kim, Elizabet	th (b) (6)	) >: LaV	ange. Lisa	(b) (6)	: Levy, Elliot
< (b) (6)	Mellors, John <	(b) (6) N	Menon, Sandee	ep q	(b) (6)	>; Parker,
Ashley (NIH/OD) [E] <	(b) (6)	>; Patel, Naim	ish	(b) (6)	Pepperco	rn, Amanda
< (b) (6)	Poole,	Mike <	(b) (6)	Pro	schan, Mich	ael
(b) (6)	Read, Sarah	(b) (6)	; Santos,	Michael (FNIH)	[T] (b)	(6) >Shen,
Yuan Li (FDA/CDER)	(b) (6)	Stein, Pe	eter (FDA/CDEF	(b)	(6)	Higgs, Elizabeth
(b) (6)	; Koroshetz, Walter	(b)	(6)	; Farley, John	(b) (	6)
(b) (6) > Timothy (b) (	(b) (6)	; Qa	shu, Felicia	(b) (6)	>; Burge:	ss,
Timothy (b)	(6) >; Re	eineck, Lora	(b) (6)	; Aggarwal	, Neil<	(b) (6)

Subject: ACTION: Making your ACTIV Participation Public

## Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.

Thanks, Francis

Francis Collins, MD, PhD NIH Director From:

Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]

Sent:

5/11/2020 4:46:34 PM

To:

CC:

Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wood, Gretchen (NIH/OD)

[E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs] Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]

Subject:

RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

I'll send her the invite and copy her assistant, Rebecca.

## Cheryl Melencio

Administrative Manager, Research Partnerships Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] <

Sent: Monday, May 11, 2020 12:46 PM

To: Wood, Gretchen (NIH/OD) [E] <

(b) (6)

(b)(6)

(b)(6)

Melencio, Cheryl (FNIH) [T] <

(b) (6)

Cc: Hardesty, Rebecca (NIH/OD) [C] <

Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl – should I forward the invite or would you prefer to add on your end?

Thank you, Ashley

From: Wood, Gretchen (NIH/OD) [E] (b) (6) Sent: Monday, May 11, 2020 9:23 AM To: Collins, Francis (NIH/OD) [E] >; Fauci, Anthony (NIH/NIAID) [E] < >; Gibbons, (b)(6)(b)(6)Gary (NIH/NHLBI) [E] >; Stoffels, Paul < PSI (b) (6) (b) (6) Pao, William ; Dolsten, Mikael >; Colvis, Christine (NIH/NCATS) [E] (b)(6)(b)(6): Desrosiers, Betsy Hughes, Eric (b)(6)(b)(6)Jansen, Kathrin Kurilla, Michael (NIH/NCATS) [E] (b)(6)(b)(6)Lowy, Douglas (NCI) < Read, Sarah (NIH/NIAID) [E] (b)(6)(b)(6)(b) (6) Young, John (b) (6)

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Menetski, Joseph (FNIH) [T] <
Cc: Wholley, David (FNIH) [T] <
                                       (b) (6)
                                                                                           (b) (6)
                                                                                                          Adam, Stacey
                                                                               ; Santos, Michael (FNIH) [T]
(FNIH) [T]
                 (b) (6)
                             : Tountas, Karen (FNIH) [T]
                                                                 (b) (6)
                                                                     Tabak, Lawrence (NIH/OD) [E]
<
                      Freire, Maria (FNIH) [T]
                                                      (b) (6)
        (b) (6)
(
                                                                              >; Parker, Ashley (NIH/OD) [E]
                           ; Lane, Cliff (NIH/NIAID) [E]
                                                                (b) (6)
þ
          (b) (6)
                          : Anderson, James (NIH/OD) [E]
                                                                      (b)(6)
                                                                                        ; Austin, Christopher (NIH/NCATS)
[E]
           (b)(6)
                          >; Melencio, Cheryl (FNIH) [T]
                                                                 (b) (6)
Subject: Re: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs
```

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

#### Gretchen

***************************************							
From: Fr	rancis Collins	(b) (6)					
Date: Sa	turday, May	9, 2020 at 1:07 PM	1				
To: Fran	cis Collins <	(b) (6)	Anthony Fa	uci <	(b) (6)	"Gibbo	ns, Gary (NIH/NHLBI)
[E]" <	(b) (6)	, 11	(b) (6)	<	(b) (6)	Gretchen	Wood
<	(b) (6)	"Pao, William"	< (b)	(6)		(b) (6)	1
<	(b) (6)	"Colvis,	Christine (NIH)	/NCATS) [	E]" <	(b) (6)	"Desrosiers,
Betsy"		(b) (6)	"Hughes,	Eric" <	(t	) (6)	"Jansen, Kathrin"
<	(b) (6)	"Kurilla,	Michael (NIH/I	NCATS) [E	]" <	(b) (6)	"Lowy, Douglas
(NCI)" <	(b) (6)	"Read, Sarah (	NIH/NIAID) [E]	" <	(b) (6)	"Young,	John"
<	(b) (6)						
Cc: Davi	d Wholley <	(b) (6)	, "Menetski, J	oseph (FI	> "[T] (HIV	(b) (6)	"Adam, Stacey
(FNIH) [	T]" (b)	(6) , "Tounta	is, Karen (FNIH	) [T]" <	(b) (6)	"Santo	s, Michael (FNIH) [T]'
<	(b) (6)	Maria Freire <	(b) (6)	"Tabal	, Lawrence	(NIH/OD) [E]"	
(b		>, "Lane, Cliff	(NIH/NIAID) [	E]"	(b) (6)	>, Ashley F	Parker
<	(b) (6)	James Ander	son <	(b) (6)		"Austin, Christ	opher (NIH/NCATS)
[E]"	(b) (6)	, "Melencio	, Cheryl (FNIH	) [T]"	(b) (6)	Greto	hen Wood
	(b) (6)	(					

Subject: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. There are also concerns about how we should best communicate across our partnership and coordinate with the many parallel (and in some cases conflicting) efforts that have emerged elsewhere—including among our own ACTIV members.

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regard	Thanks for	all you ar	e doing t	for the	cause,	and	best	regards
---	------------	------------	-----------	---------	--------	-----	------	---------

Francis

Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC] 11/12/2020 5:10:25 PM Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Bancel, Stephane (b)(6)Carter, Kara 1 (b) (6) Cavaleri, Marco Cihlar, Tomas [ Collins, Francis (NIH/OD) [E] (b) (6) (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Dolsten, Mikael Erbelding, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldingej]; Erck, Stan Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn : Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh (b) (6) Pangalos, Mene | (b)(6)Pao, William Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Paul, Steve (b) (6) Perlmutter, Roger [ (b) (6) Plenge, Robert | Plump, Andy [ Rachel Ramoni [/o=ExchangeLabs/ou=Exchange Administrative Group (b)(6)(FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramo]; Rasi, Guido (b) (6) Reed, John (b) (6) Reese, David [ (b) (6) Rouse, Doris Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul (b)(6)Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Talley, Michael (b) (6) Tsai, John (b) (6) Vessey, Rupert | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John

From:

Sent:

To:

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Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative
                         (b) (6)
              Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
                                              ]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin
                                         Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
              [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
CC:
              Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John
              (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowi]; Carluccio, Dana
                             (b) (6)
                                                  Castilleios, Carlos I
                                                                           (b) (6)
                                                                                        FNIH Central Account
                        (b)(6)
                                         Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Myles, Renate (NIH/OD) [E]
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              (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD)
              [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Adam, Stacey (FNIH) [T]
              [/o=ExchangeLabs/ou=Exchange Administrative Group
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              [/o=ExchangeLabs/ou=Exchange Administrative Group
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              [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen,
              Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange
              Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina
              [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk,
              Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group
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                                                                                           (b) (6)
                                                                                                            asorosa
              [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86];
              Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative
              Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T]
              [/o=ExchangeLabs/ou=Exchange Administrative Group
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                                    ]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH)
              [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Austin, Sarah (NIH/NIAID)
              [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly
              (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie
                                        ]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative
              Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
              [/o=ExchangeLabs/ou=Exchange Administrative Group
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                                                                                Conrad, Patricia (NIH/NIAID) [E]
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                                        Coan, Amanda
                                                                (b) (6)
              [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne
              (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
              (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan
                                     Fuhrer, Nicole |
                                                                               Giorgi, Sara |
                      (b)(6)
                                                              (b) (6)
                                                    Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
              Hoban, Michelle
                                      (b)(6)
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Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter];

Iberdemaj, Vaide | Jenkins, Christine S. (b)(6)(b) (6) Krack, Kimberly [kimberly]; (b)(6)Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Lever, Susan | McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange (b) (6) Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth [ Perala, Mie | ]; Protasiewicz, Ann (b)(6)(b)(6)Riccobene, Kim | Riggin, Mary | (b)(6)(b)(6)(b) (6) Sepulveda, Ripley, Nadege | Schuster, Donna | (b) (6) (b)(6)Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Tajalli, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashim]; Underwood, Nancy (b)(6)Zottoli, Jessica | (b) (6)

Subject: ACTIV Leadership Team Meeting #11

Location: https://fnih.zoom.us/ (b) (6)

Start: 12/16/2020 3:00:00 PM End: 12/16/2020 4:00:00 PM

Show Time As: Busy

## Required Attendees:

Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Rasi, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

### Optional Attendees:

Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina

(NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR] Sent: 6/30/2020 7:18:04 PM To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Lowy, Douglas (NIH/NCI) [E] [ (b)(6)(b) (6) Beth Bell ( (b)(6)Arvin, Ann [ (b) (6) (b) (6) Cavaleri Marco ( (b)(6)(b) (6) (b) (6) Greg Glenn [ (b)(6)(b) (6) (b) (6) Havnes, Barton | (b) (6) (b)(6)(b) (6) (b)(6)Marks, Peter (FDA/CBER) [ Mascola, John (NIH/VRC) [E] [ (b) (6) (b)(6)Messonnier, Nancy (CDC/DDID/NCIRD/OD) | (b)(6)Nelson Michael | il]; (b)(6)Offit, Paul | Seals, Jonathan (OS/ASPR/BARDA) [ (b)(6)(b)(6)Tal Zaks (b)(6)(b) (6) (b)(6)(b)(6)CC: Tolman, Brett [ (b)(6)Hopps, Markay | (b)(6)(b)(6)Kozlowski, Mary (NIH/NCI) [C] | ]; Johnson, Maureen (NIH/NCI) [E] (b)(6)Jeneffer Haynes | (b) (6) (b)(6)(b) (6) Austin, Sarah (NIH/NIAID) [E] (b) (6) (b) (6) (b) (6) (b)(6)(b) (6) Isabel Ramsev (b) (6) Parker. Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary (NIH/NIAID) [E] [ Qashu, Felicia (NIH/OD) [E] [ Culp, Michelle (b)(6)(b)(6)(NIH/OD) [E] [ Gadbois, Ellen (NIH/OD) [E] | Wholley, David (FNIH) [T] (b)(6)(b) (6) Menetski, Joseph (FNIH) [T] Melencio, Cheryl (FNIH) [T] | (b)(6)(b)(6)(b) (6) Adam, Stacey (FNIH) [T] | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6) James, Stephanie (FNIH) [T] [ (b)(6)Colvis, Christine (NIH/NCATS) [E] | (b)(6)Desrosiers, Betsy Hughes, Eric | Kurilla, Michael (b)(6)(b)(6)Read, Sarah (NIH/NIAID) [E] [ Paul Gillard (NIH/NCATS) [E] [ (b) (6) (b) (6) Hamilton, Holli (OS/ASPR/BARDA) | Modiarrad, Kayvon CIV (b)(6)(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) USARMY MEDCOM WRAIR (USA) | (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [ (b)(6)Thornburg, Natalie (b) (6) (CDC/DDID/NCIRD/DVD) [ 'Wachtel, Jonathan' | Stratton, Benjamin (b)(6)(b)(6)rose. dana.car **Bethany Stokes** (b)(6)(b) (6) (b)(6)Kathleen Callahan | Gallo, Robert (b) (6) (b)(6)(b)(6)Kottilil, Shyamasundaran I (b)(6)Chumakov, Konstantin (FDA/CBER) [ Konstantin Chumakov | Miller, Elissa (b)(6)(b) (6) (b) (6) Pfeiffer, Frank | Jacqueline Miller (b) (6) Jessica Cowden Arvin, Ann (b)(6)(b)(6)Kathleen Neuzil Young, John [ (b)(6)(b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Anderson, Margaret | (b)(6)Subject: **ACTIV Vaccines Working Group meeting** Location: Webex: https://nih.webex. (b)(6)Start: 7/13/2020 4:00:00 PM End: 7/13/2020 5:00:00 PM Show Time As: Busy Required Santos, Michael (FNIH) [T]; (b)(6)Lowy, Douglas (NIH/NCI) [E]; (b)(6)Attendees: Arvin, Ann; Beth Bell ( Cavaleri Marco; (b)(6)(b) (6) (b) (6) (b)(6)Greg Glenn; (b)(6)Haynes, (b) (6)

	Barton;	(b) (6)	(b)	(6) Marks, Peter	(FDA/CBER); Maso	cola, John	(NIH/VRC) [E];		
	Messonni	er, Nancy (C	DC/DDID/NCIRD,	(OD); Nelson Michael; Off	it, Paul; (b)	(6)	Seals, Jonathan		
	(OS/ASPR,	/BARDA);	(b) (6)	(b)	(6)	Tal Zaks			
Optional	Tolman, B	rett;	(b) (6)	Hopps, Markay; Kozlo	wski, Mary (NIH/N	VCI) [C]; J	ohnson, Maureen		
Attendees:	(NIH/NCI)	[E];	(b) (6)	Jeneffer Haynes;	(b) (6)		(b) (6)		
		(b) (6)	Austin, Sara	h (NIH/NIAID) [E];	(b) (6)		Isabel Ramsey; Parker,		
	Ashley (NI	Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];							
	Gadbois, E	Ellen (NIH/O	D) [E]; Wholley, I	David (FNIH) [T]; Melencio	, Cheryl (FNIH) [T]	; Menets	ki, Joseph (FNIH) [T];		
	Adam, Sta	cey (FNIH) [	T]; Tountas, Kare	n (FNIH) [T]; James, Steph	anie (FNIH) [T]; Co	olvis, Chri	stine (NIH/NCATS) [E];		
	Desrosiers, Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul								
	Gillard; Ha	amilton, Hol	li (OS/ASPR/BARI	DA); Modjarrad, Kayvon C	IV USARMY MEDC	OM WRA	IR (USA); Kathleen Neuzil		
	Schrag, St	ephanie (CD	C/DDID/NCIRD/I	OBD); Verani, Jennifer R. (	CDC/DDID/NCIRD/	DBD); The	ornburg, Natalie		
	(CDC/DDII	D/NCIRD/D\	D); Gonzalez, Ni	na; Wachtel, Jonathan; Str	ratton, Benjamin;	Anderson	, Margaret;		
		(b) (6)		(b) (6)	Bethany Stok	es; Kathle	en Callahan; Gallo,		
	Robert; Ko	ottilil, Shyan	nasundaran; Chu	makov, Konstantin (FDA/C	BER); Konstantin (	Chumako	v; Miller, Elissa; Pfeiffer,		
	Frank: Jac	queline Mill	er Cowden less	ca J Col USAF AFMSA (USA	Al: Ann Arvin				

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4] Sent: 5/16/2020 8:37:37 PM To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; Collins, Sylva (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner Keith Gottesdiener I Eric Hughes (b) (6) (b) (6) (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy (b)(6)Sandeep Amanda Peppercorn | Menon | (b)(6)(b)(6)Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn (b)(6)Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael Wung, Peter /US [ Karen Lynn Price (b) (6) (b) (6) Pamela Tenaerts, M.D. | (b) (6) Patterson, Amy (NIH/NHLBI) [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy Beumont-Mauviel, Maria [JRDUS] [ Peeters, Monika [JRDBE] (b) (6) (b) (6) (b)(6)Woodfall, Brian [JRDUS] [ (b) (6) ]; Van Heeswijk, Rolf [JRDBE] (b)(6)CC: Macone, Erin | Mary Biggs (b) (6) Demarcus (b)(6)(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan Elizabeth Kim [ (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc] Subject: Note about ACTIV TX-Clinical Master Protocol Subgroup Meeting #19

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Similarly to my last note, many of you will see this meeting disappear from your calendar as well. We will be repurposing this for another discussion with the SARS-CoV-2 neutralizing mAbs subteam.

Thank you for your understanding and we look forward to updating you all on our progress on Thursday and Friday.

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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	(b) (6)		(b) (6)	Shannon	Devine [	(b) (6)			
Subject:	Agenda for the Va	ccines Clinic	al Trials Sub-Group m	eeting tom	orrow				

Dear Vaccines Clinical Trials Sub-Group,

We're looking forward to our meeting tomorrow (Monday), at 12pm ET (9am PT / 6pm CST).

The topic for discussion will be the potential to conduct blinded cross-overs of placebo control group phase 3 trial participants to active controls. We will be joined by Dean Follmann of NIAID and Lindsey Baden of Harvard who will present potential approaches for discussion.

Please feel free to reach out with any questions or suggestions.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Sunday, November 22, 2020 7:09 PM

Subject: Notes from the Vaccines Clinical Trials Sub-Group meeting

Dear Vaccines Clinical Trials Sub-Group,

Thank you for your participation in our last meeting, and particular thanks to Larry, Audrey, and Holly for leading the discussion.

Notes from the meeting with the presentation embedded are attached. As a reminder, if you have additional feedback for the group working on the design of this study, please either reach out to them directly or send it to us and we will pass it along.

We welcome your questions or suggestions any time.

Best regards, Brett and Mike

Michael Santos, PhD

Associate Vice President, Science Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]

Sent: Wednesday, November 18, 2020 8:02 AM

Subject: Agenda for the Vaccines Clinical Trials Sub-Group meeting today

Dear Vaccines Clinical Trials Sub-Group,

We're looking forward to our meeting today, at 1pm ET (10am PT / 7pm CST).

The topic for discussion will be the potential to evaluate the impact of vaccines on transmission. We will be joined by Audrey Pettifor of UNC and Holly Janes of Fred Hutch, who with Larry Corey will present potential approaches for discussion.

Please feel free to reach out with any questions or suggestions.

Best regards, Brett and Mike

Michael Santos, PhD Associate Vice President, Science

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Start: 2/18/2021 6:00:00 PM End: 2/18/2021 7:00:00 PM

Recurrence: (none)

Required Attendees:

To:

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Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterton, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Jacqueline Kirchner;

Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;

(b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina;

Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio;

Rose Li Central Account; Lucas Smalldon;

(b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD)

[E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.;

Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei

(NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA);

Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID)

Optional

Attendees:

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              Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Dear ACTIV O	utpatient mAbs Writi	ng Team,								
Please find at	tached the notes fron	n today's meeting that Eliza	beth did a grea	t job in capturii	ng. While I know v	ve would				
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In addition, we wanted to set another meeting of these team for tomorrow. I have discussed with Karen and Lisa and they think they could have some thoughts together for the group's response by 4pm tomorrow. Would this group be able to meet from 4-5pm ET tomorrow?

Finally, the ACTG team that has been working on the base protocol would like to hear any other feedback not covered in the action items above from the group, so if you all can review and be ready to provide thoughts or send them in redline and comments ahead of the meeting, that would be perfect. (Document attached once again for ease of reference.)

Once again, thank you all for being willing to come together and get this protocol revised to fit the capacity needs of this new venture!

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer Research Partnerships

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From:

Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

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Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD)

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CC:

Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]

Subject:

FW: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Attachments: Coagulation COVID19 panel roster BARDA30 April 2020 v042620.docx; Pulmonary-ARDS Expert Panel.docx; renal

panel roster.docx; Immunoinflammatory panel roster.docx

News—members of our TX-Clinical WG have been invited to an ad hoc BARDA panel to look at anticoagulants that could be accelerated. Cliff, I thought you might be particularly interested in hearing this given your recent comments in our war room calls. By the way Tim Buchman has been a very active and vocal participant on the ACTIV WG calls.

From: Adam, Stacey (FNIH) [T] <

(b) (6) Sent: Wednesday, April 29, 2020 9:56 AM

To: Wholley, David (FNIH) [T] <

(b) (6)

Subject: FW: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Hi David,

Per my last note, here is the updated information and invite from our BARDA rep.

Thanks,

Stacey

Stacev J. Adam, PhD

Director, Cancer

Research Partnerships

Direct:

(b) (6)

Mobile:

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From: Buchman, Tim (OS/ASPR/BARDA) (CTR) <

(b) (6)

Sent: Wednesday, April 29, 2020 9:51 AM

To: Read, Sarah (NIH/NIAID) [E] <

(b) (6)

Koroshetz, Walter (NIH/NINDS) [E]

< (b)(6)

Cc: Adam, Stacey (FNIH) [T] <

(b) (6)

Hughes, Eric <

(b) (6)

Subject: RE: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Dear Sarah and Walter, cc: Eric and Stacey,

Good morning, no problem.

Let me also mention something else that may be useful to you.

For the past three weeks, I have been assembling panels of national/international experts for BARDA to discuss "where things stand" and "what's needed" assorted by organ systems. These are truly blue ribbon panels. Thus far there are four: immunoinflammatory; renal; pulmonary/ARDS; and coagulation.

By happy coincidence, the coagulation panel convenes tomorrow (Thursday) at 1100-1200. The roster is among the four that I have included with this email, and really is the "who's who" in the coagulation world. I will be on the call of course, and it occurs to me that you (plural) might want to join if able. I think it might give some insight into how those who are global experts and also in the front lines are seeing the hematopathology, the clinical realization, and where they think the best therapies might lie.

Let me know if you are interested. It will be a large call line and you can choose to identify yourselves or not.

If you want access to anyone on any of these panels, please let me know and I will be delighted to facilitate.

Tim

Timothy G. Buchman, PhD, MD

Senior Advisor

IPA to the DRIVe (Division of Research, Innovation and Ventures)

Biomedical Advanced Research and Development Authority (BARDA)

Office of Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (HHS)

Thomas P. O'Neill, Jr. Federal Building (FOB8)

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Washington, DC 20024

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From: Read, Sarah (NIH/NIAID) [E] < (b)(6)

Sent: Wednesday, April 29, 2020 8:59 AM

To: Koroshetz, Walter (NIH/NINDS) [E] < Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6)

(b)(6)

Cc: Adam, Stacey (FNIH) [T] < : Hughes, Eric < (b) (6) (b)(6)

Subject: FW: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Importance: High

Hi Walter and Tim,

I am joining you as a scorer for anticoagulants but am no expert! I'd like to see if we can take advantage on your knowledge and experience and ask if you think there should be other candidates on our list. If so, will you please share those amongst our scoring group so we can score them as well?

Thanks!

From: Adam, Stacey (FNIH) [T] < (b) (6) Sent: Wednesday, April 29, 2020 8:34 AM To: Eric Hughes < Read, Sarah (NIH/NIAID) [E] < Ruxandra Draghia-(b)(6)(b)(6)Akli < Mellors, John W < (b)(6)Naimish Patel < (b)(6)Colvis, (b) (6) Christine (NIH/NCATS) [E] < (b)(6)Young, John < Stein, Peter (b) (6) (FDA/CDER) < (b)(6)Poole, Mike < (b)(6)Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b)(6)Wung, Peter/US (b) (6) Vincent, Michael < (b) (6) Keith Gottesdiener < (b) (6) Elliott Levy < (b)(6)Koroshetz, Walter (NIH/NINDS) [E] < Higgs, Elizabeth (NIH/NIAID) [E] (b) (6) (b)(6)Cc: Elizabeth Kim < Menetski, Joseph (FNIH) [T] < (b) (6) Alvarez, Rosa Maria (b)(6)Salathin, Carla < (b)(6)(b)(6)Parker, (b)(6)(b) (6) Ashley (NIH/OD) [E] < Wholley, David (FNIH) [T] < Melencio, Cheryl (FNIH) (b) (6) (b)(6)Lucas Smalldon < [T] < (b)(6)(b)(6)

Subject: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

Thank all once again for a very productive and educational discussion yesterday. We truly appreciate all the time and effort you are committing to this.

With our tie-breaker votes in (thanks Walter) and the discussion yesterday. I think we have the list for scoring down to a very manageable number, and as decided yesterday, we will breakup the list into agent subclasses and have just a subset of reviewers score each subclass that they personally feel they are well qualified to review: antivirals, host targeted/immune modulators, and symptomatic/supportive therapies. You all were kind enough to email me your choices so our group will be broken down into the following review groups:

#### **Antivirals**

Libby Higgs

John Young

Ruxandra Draghia-Akli

John Mellors

#### Host Targeted/Immune Modulators

Group 1

Eric Hughes

Naimish Patel

Elliott Levy

Group 2

Mike Vincent

Peter Wung

Keith Gottesdiener

### Symptomatic/Supportive

Sarah Read

Walter Koroshetz

Tim Buchman

You will notice that the Host Targeted/Immune Modulators reviewers are broken into 2 groups. This is because they ended up with the largest number of agents and the broadest categories of mechanisms. Therefore, we are splitting the agents and the review group in half to allow them to complete a thorough review in the short timelines that we are

shooting for. You will see that the score sheet for the Host Targeted/Immune Modulators has also been split accordingly.

As described yesterday, in the attached spreadsheet you will find the final triage report with all the rationale from the original triage to the right of the "Keep/Drop" column. This may or may not be helpful in your reviews. I am also once again attaching the compiled data spreadsheet such as it is, knowing that it may be helpful to some and some may choose to do their own research. However, both this and the clinical trials report are attached for those who will find them useful.

For the instructions for scoring, these are simple.

- 1. Open the ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1 and then find the appropriate tab for the group above that you have selected to score.
- 2. Review your compounds according to all criteria across the top of the sheet and the scoring rubric within the drop-down menus for each criteria. With one exception, if the availability of the compound is unknown to you, you may leave this criteria blank and we will work to figure this out after the highest ranking agents are selected.
- Record your scores in the spreadsheet.
- 4. Return the spreadsheet to myself and Elizabeth Kim ( by 8 am, Friday, May 1, if at all (b) (6) possible. (If you are going to miss this deadline, please let us know by Thursday evening so we can plan accordingly.)
- Elizabeth and I will then tally the scores and prepare the reports for our meeting on Friday afternoon for discussion and any adjudication necessary by the group.

As always, if you have any questions or need anything from us that we can help with, please do not hesitate to reach out. We will also have a meeting on Thursday afternoon to address any questions the group might have ahead of finalizing your score sheets. This will also allow our advisory members to weigh in on the lists, as well.

Thank you in advance for all your hard efforts!

Thanks, Stacey

Stacey J. Adam, PhD

Director, Cancer

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